Unrelated Donor/Patient Confidential Information Standard Operating Procedure

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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.

MATERIALS
2. Confidentiality Guidelines for Working with the Media (network website).
4. Confidential Information SOP Table (A00696).
5. Guidelines for Social Media Sharing (network website).
6. Identifying Quality Incidents (S00348).
7. Quality Management System Overview (S00370).
8. International Policies Regarding Post-Transplant Communications Between Donors and Recipients (network website).
12. Post-Transplant Consent Request Form (F00782).
14. Reporting a Quality Incident in MasterControl (S00371).
15. Social Media and Social Networking Engagement Policy and Guidelines (P00091).

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 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 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
See Procedures section of this SOP for specific responsibilities.
PROCEDURES

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. When disclosure is permitted, it 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 Incident.

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, text messages, e-faxes, e-forms, or other similar communications), such persons or entities must:

1.2.1.1.1. Use Primary Donor Identifier(s) and RID (Recipient ID number) instead of names, whenever possible.

1.2.1.1.2. Use NMDP email (which is secure by default) for correspondence containing Donor-Identifying Information or Patient-Identifying Information.
Information when corresponding with contracted NMDP Network partners.

1.2.1.3. Use NMDP “Send Securely” email feature for correspondence containing Donor-Identifying Information or Patient-Identifying Information when corresponding with any party which is not a contracted NMDP Network partner (without limitation, examples include Donors, Patients, independent home health care agents, independent physicians, and non-NMDP-Network centers).

1.2.1.4. Not use Donor-Identifying Information or Patient-Identifying Information in email or e-fax subject, title, or description lines. Use of Primary Donor Identifier(s) or RID is acceptable.

1.2.1.5. 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 Primary Donor Identifier(s) 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-Identifying Information in secure/locked chambers or locked file storage.

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 and Related Information by NMDP Patient Advocacy and Navigation**

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 Navigator 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 the persons identified in § 1.3.1. 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 Advocacy and Navigation 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 Advocacy and Navigation.
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. Irrespective of a Patient’s consent to allow disclosure of information, any information on the detailed search activity of a Patient’s search cannot be shared with persons under § 1.3.2 and its subparts. 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 Advocacy and Navigation 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 Navigator 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.

1.4. Disclosure of Donor-Identifying Information or Patient-Identifying Information in the Search Process

1.4.1. Donor-Identifying Information or Patient-Identifying Information may be disclosed in the search process, only as detailed in this subsection.

1.4.1.1. Initial Stages of Search Activity (DR Typing, HR Typing, CT): Patient-Identifying Information

1.4.1.1.1. Donors other than cord blood Donors may be provided only with the following Patient-Identifying Information: gender, age, diagnosis and disease status. Cord blood Donors may not be provided with any Patient-Identifying Information.

1.4.1.2. Initial Stages of Search Activity (DR Typing, HR Typing, CT): Donor-Identifying Information

1.4.1.2.1. The Patient and Patient’s family must not be provided with Donor-Identifying Information at these
stages, except as may be provided herein.

1.4.1.2.2. Transplant Centers may be provided with the following Donor-Identifying Information: Donor HLA type and locations of matches or mismatches; Primary Donor Identifier(s); Donor gender, date of birth, blood group and Rh antigens (ABO/Rh type), infectious disease marker (IDM) results, and genetic hemoglobin abnormalities; country in which the Donor Center, registry, or cord blood bank is located; managing Donor Center; and for cord blood donations, maternal and family medical history questionnaire information and identification of the cord blood bank.

1.4.1.2.2.1. Where necessary for clinical and/or informed consent purposes, the Transplant Center may share the following information with the Patient: Donor HLA type and locations of matches or mismatches; Donor gender, age, and blood group and Rh antigens (ABO/Rh type); and genetic hemoglobin abnormalities.

1.4.1.2.3. In some cases involving additional Patient risk or expense arising from a Donor's medical/health condition, the Transplant Center may need to review and approve certain Donor medical/health risk information before proceeding with the transplant. In such cases, only the information necessary for the Transplant Center and Patient to
make an informed decision may be shared.

1.4.1.2.4. NMDP may share with the Transplant Center only information pertinent to Patient clinical decision-making. In the case of Donor unavailability, no information or assumptions as to why the Donor is unavailable may be provided to the Patient, the Patient’s family, or others.

1.4.1.2.5. The Transplant Center must not disclose the exact timeframe of any Donor unavailability to the Patient or the Patient’s family. No information or assumptions on why the Donor is unavailable may be provided by Transplant Center staff to the Patient, the Patient’s family, or others.

1.4.1.3. Workup Stage of Search Activity: Patient-Identifying Information

1.4.1.3.1. Donors other than cord blood Donors may be provided only with the following Patient-Identifying Information: gender, age, diagnosis and disease status. Cord blood Donors may not be provided with any Patient-Identifying Information.

1.4.1.3.2. Patient information that is necessary to determine a collection date may be shared with the Donor Center and/or Apheresis or Collection Center, by NMDP staff.

1.4.1.3.3. After or in conjunction with product selection, NMDP Donor Center staff and network Donor Center staff may provide the Apheresis Center, Collection Center, or Cord Blood Bank with certain Patient-Identifying Information that is necessary to confirm product identification and support product distribution/transport; the information is limited to Patient name, date of birth, gender, diagnosis, and/or managing
1.4.1.4. Workup Stage of Search Activity: Donor-Identifying Information

1.4.1.4.1. Once a Donor has been cleared for donation, the Patient may be provided with the following Donor-Identifying Information: Donor gender and age.

1.4.1.4.1.1. Where necessary for clinical and/or informed consent purposes, the Transplant Center may also share the following information with the Patient: Donor HLA type and locations of matches or mismatches; Donor blood group and Rh antigens (ABO/Rh type); and genetic hemoglobin abnormalities.

1.4.1.4.2. NMDP may share with the Transplant Center information that is pertinent to Patient clinical decision-making or to determine a collection date. If a Donor is unavailable, NMDP staff may inform the Transplant Center by providing only the information necessary to determine probability and timing of the Donor being able to proceed.

1.4.1.4.3. The Transplant Center must not disclose the exact timeframe of any Donor unavailability to the Patient or the Patient’s family. No information or assumptions on why the Donor is unavailable may be provided by Transplant Center staff to the
Patient, the Patient’s family, or others.

1.4.1.4.4. In some cases involving additional Patient risk or expense arising from a Donor’s medical/health condition, the Transplant Center may need to review and approve certain Donor medical/health risk information, including through the Abnormal Findings process, before proceeding with the transplant. In such cases, only the information necessary for the Transplant Center and Patient to make an informed decision may be shared.

1.5. **Stem Cell Transport**

1.5.1. All couriers must maintain the confidentiality of Donor-Identifying Information and Patient-Identifying Information and must undergo training on the Confidential Information Policy, this Confidential Information SOP, courier policies and procedures, and any other applicable policy or procedures.

1.5.2. Couriers must use extreme care to avoid inadvertently compromising anonymity of the Donor and Patient.

1.5.3. Important considerations for maintaining Donor and Patient confidentiality in relation to stem cell transport include:

1.5.3.1. **Product labels:** Couriers and NMDP Network members shall not make any identifying information or markings on labels or packaging materials available or accessible to the Donor or the Recipient. That includes but is not necessarily limited to Donor or Recipient name and/or the locations or names of the Donor Center or Cooperative Registry, or the Transplant Center.

1.5.3.2. **Gifts/correspondence:** Couriers may not deliver gifts or correspondence.

1.5.3.2.1. If a courier is asked to deliver gifts or correspondence, he or she must decline the request and inform the NMDP Logistics personnel of the request, upon delivery of the product.

1.5.3.2.2. On being informed of such a request by a courier, NMDP Logistics personnel must compile preliminary information on a Problem
Management Form and submit it to the NMDP Quality Management System.

1.5.3.3. Casual conversation: At all times while transporting stem cells, couriers must take care when engaging in casual conversation. Couriers should not identify where the stem cells originated or their destination and shall not discuss any information about the Donor or Patient.

1.5.3.4. Media attention: Refer to the subsection below, entitled “Working with the Media.”

1.6. Donor/Recipient Contacts

1.6.1. Donor/Recipient Contacts – Cord Blood

1.6.1.1. The identity of cord blood Donors always remains Confidential. Therefore, contacts between cord blood Donors and cord blood Recipients are not permitted at any time.

1.6.1.2. A Recipient wishing to express gratitude to his or her Donor may be encouraged to provide a general letter or other correspondence to the National Marrow Donor Program, the Health Resources and Services Administration, or other appropriate organization.

1.6.2. Donor/Recipient Contact Prior to Transplant

1.6.2.1. Contact between Donors and Patients is not permitted prior to transplant.

1.6.3. Donor/Recipient Contacts in the First Year After Transplant

1.6.3.1. Donor-Identifying Information and Patient-Identifying Information must remain Confidential for at least one year following the date of transplant. Therefore, the Donor and Recipient may not have direct contact during the first year after transplant.

1.6.3.2. Center coordinators are responsible for determining whether anonymous Donor and Recipient exchanges will be allowed in this period. If they are allowed, the Donor and Recipient may exchange items and correspondence that do not disclose Donor-Identifying Information or Patient-Identifying Information.

1.6.3.2.1. International Centers and Cooperative Registries may have additional or unique requirements for Donor/Recipient contacts, including different timing for those contacts or other limitations or prohibitions on
contacts. Center coordinators therefore must review potentially-applicable policies or procedures of non-U.S. centers before any Donor/Recipient exchanges are facilitated.

1.6.3.2.2. Throughout Donor workup, Patient pre-transplant evaluation, and after donation and transplant, the center coordinators are responsible for being aware of the correspondence and gift exchange rules at the receiving center, and for ensuring their Donor or Recipient is appropriately counseled about contacts at relevant and appropriate times.

1.6.3.2.3. Refer to the NMDP “International Policies Regarding Post-Transplant Communication Between Donors and Recipients,” for guidance on what is acceptable to different Cooperative Registries and International Centers. Center coordinators also may contact the NMDP Post Transplant Communication Team, in Patient Advocacy and Navigation, for questions specific to each center.

1.6.3.2.4. Where contacts are appropriate, center coordinators additionally are responsible for complying with other requirements of this SOP.

1.6.3.3. Center coordinators are responsible for counseling the Donor or Recipient about acceptable and unacceptable content in anonymous correspondence and/or gifts. Center coordinators may refer Donors or Recipients to BeTheMatch.org for additional guidance on acceptable correspondence content and gifts.

1.6.3.4. The center coordinator at the originating center is responsible for initial screening of correspondence and gifts that Donors or Recipients seek to exchange. The NMDP “Anonymous Correspondence and Gifts: Policies and Procedures” provide specific details on appropriate
screening and handling of anonymous correspondence and gifts.

1.6.3.5. If the correspondence or gift is acceptable, in its original or modified form, the center coordinator then must forward it to the NMDP Post Transplant Communication Team.

1.6.3.6. The NMDP Post Transplant Communication Team will document the receipt date for items and review the sending and receiving centers’ exchange rules. If the rules at a center, including a Cooperative Registry or International Center, do not allow the correspondence or gifts, the items will be returned to the originating center.

1.6.3.7. The NMDP Post Transplant Communication Team will review all items and correspondence and remove any remaining Donor-Identifying Information or Patient-Identifying Information, as well as other information that could lead to such identifying information, before forwarding to the receiving center for delivery to the Donor or Recipient. The NMDP “Anonymous Correspondence and Gifts: Policies and Procedures” provide specific details on appropriate screening and handling of anonymous correspondence and gifts.

1.6.3.8. Subsequent Donations (Within the First Year After Transplant)

1.6.3.8.1. When a subsequent donation is requested from the same Donor and for the same recipient, within the first year after transplant, the period for Donor/Recipient anonymous contacts continues for an additional sixty (60) days after resolution of the subsequent donation request and transplant, or until the expiration of the original one year period after the first transplant, whichever is longer.

1.6.3.9. Exception Process for Contacts in the First Year After Transplant

1.6.3.9.1. Exceptions to the NMDP requirements in this section should be requested, and will be approved, only in highly unusual circumstances.
1.6.3.9.2. Requests for exceptions to these requirements shall be submitted in writing to the Donor Advocacy Manager.

1.6.3.9.3. All requests for exceptions will be evaluated and decided by the NMDP Chief Executive Officer or his/her designee. Requests for exceptions also will be raised with the Health Resources and Services Administration, which shall have three (3) business days to comment on any proposed exception.

1.6.3.9.4. Contacts requiring exceptions cannot proceed while an exception is being considered. Advance approval for the contacts is required.

1.6.3.9.5. If an exception is approved, the remaining requirements of this section must be followed. Exceptions approved by NMDP do not necessarily constitute exceptions to requirements established by other centers or registries.

1.6.4. **Donor/Recipient Contacts Beyond the First Year After Transplant**

1.6.4.1. After one year from transplant, Donors and Recipients may be allowed to exchange Donor-Identifying Information and Patient-Identifying Information, when the Donor and Recipient both have signed appropriate consent forms.

1.6.4.1.1. Refer to the “Procedure for Obtaining Post-Transplant Consent to Release Personal Information” for the detailed procedure.

1.6.4.2. If a Donor or Recipient has expressed an interest in exchanging Personally Identifiable Information with the other party, the center coordinator must (1) determine whether the appropriate time period has passed, (2) determine whether exchange of such information is allowed by the centers and/or registries at issue, and (3) review the NMDP “Post-Transplant Consent Form to Release Personal Information” with the center’s Donor or Recipient and obtain that person’s consent.
1.6.4.2.1. International Centers and Cooperative Registries may have additional or unique requirements for Donor/Recipient contacts, including different timing for those contacts or other limitations or prohibitions on contacts. Center coordinators therefore must review potentially-applicable policies or procedures of non-U.S. centers before any Donor/Recipient exchanges are facilitated.

1.6.4.2.2. Throughout Donor workup, Patient pre-transplant evaluation, and after donation and transplant, the center coordinators are responsible for being aware of the receiving center’s rules for release and exchange of Personally Identifiable Information, and for ensuring their Donor or Recipient is appropriately counseled about release and exchange of Personally Identifiable Information at relevant and appropriate times.

1.6.4.2.3. Refer to the NMDP “International Policies Regarding Post Transplant Communication Between Donors and Recipients,” for guidance on what is acceptable to different Cooperative Registries and International Centers. Center coordinators also may contact the NMDP Post Transplant Communication Team, for questions specific to each center.

1.6.4.2.4. Where contacts are appropriate, center coordinators additionally are responsible for complying with other requirements of this SOP.

1.6.4.3. The center coordinator is responsible for reviewing the NMDP “Post-Transplant Consent Form to Release Personal Information” with the Donor or Recipient, ensuring that the Donor or Recipient understands all sections of the consent, determining what information the Donor or Recipient agrees may be exchanged within the
applicable guidelines, and obtaining the individual’s signature on the consent.

1.6.4.4. The initiating center coordinator will inform the NMDP that their Donor or Recipient has signed the consent form to exchange Personally Identifiable Information with the other party, by completing and submitting the NMDP “Post-Transplant Consent Request Form,” found on the NMDP Network Website.

1.6.4.5. Once the completed Post-Transplant Consent Form to Release Personal Information and the completed Post-Transplant Consent Request Form are received, the NMDP will contact the other center to inform them of the request. The NMDP will allow the other center at least twenty-eight (28) calendar days from the date of the request, to determine their Donor or Recipient’s interest in also consenting to release Personally Identifiable Information.

1.6.4.5.1. The receiving center coordinator for the other party has the responsibilities identified above, in evaluating and obtaining consent from their Donor or Recipient.

1.6.4.5.2. If the other party declines, is lost to follow up, or otherwise fails to respond, the initiating center will be informed, and the request will be closed.

1.6.4.5.3. If the other party also consents to release Personally Identifiable Information by completing the NMDP “Post-Transplant Consent Form to Release Personal Information,” the center coordinator will submit that consent to the NMDP Post Transplant Communication Team. Once both signed consent forms have been received, the NMDP will exchange consent forms with the respective centers.

1.6.4.5.4. The centers are responsible for maintaining copies of all consent forms.
1.6.4.6. **Subsequent Donations (Beyond the First Year After Transplant)**

1.6.4.6.1. When a subsequent donation is requested from the same Donor and for the same recipient, beyond the first year after transplant, and the Donor and Recipient have not established contact, the period for Donor/Recipient anonymous contacts continues for an additional sixty (60) days after resolution of the subsequent donation request and transplant.

1.6.4.6.1.1. Any pending release of information shall be deferred during this period.

1.6.4.6.2. When a subsequent donation is requested from the same Donor and for the same recipient, beyond the first year after transplant, and the Donor and Recipient already have established contact, no change in contacts is required.

1.6.5. **Recipient Status Updates**

1.6.5.1. NMDP asks Transplant Centers to provide limited Recipient status updates at the following intervals: 100-day survival (available nine months post-transplant); six month survival (available twelve months post-transplant); one year survival (available eighteen months post-transplant); and two year survival (available thirty months post-transplant). An automatically-generated report specific to each Donor Center will be emailed to Donor Center staff on a weekly basis. Donor Center staff may then inform the donor of his/her recipient’s status.

1.6.5.2. Some international centers/registries do not routinely release Recipient updates. The Donor Center is responsible for appropriately counseling the Donor that Recipient status updates are not always provided or available.

1.7. **Miscellaneous**

1.7.1. **Blood Samples and Buccal Swabs**
1.7.1.1. Blood samples and buccal swabs must be labeled with Primary Donor Identifier(s) or RID and not the Donor’s or Patient’s name or other Donor- or Patient-Identifying Information.

1.7.1.1.1. Notwithstanding other provisions of this SOP, Donor or Patient name and date of birth may be disclosed to the NMDP Biorepository or to service providers authorized to receive Donor or Patient samples, in conjunction with sample collection, shipment, and testing, when such identifying information is provided for Donor or Patient sample identification purposes. Information provided in this manner and for this purpose otherwise remains subject to the requirements and limitations of this SOP.

1.7.1.1.2. Notwithstanding other provisions of this SOP, Patient name may be disclosed to service providers authorized to receive Donor samples, in conjunction with sample testing and shipment, when such identifying information is provided for Donor and Patient match verification purposes. Information provided in this manner and for this purpose otherwise remains subject to the requirements and limitations of this SOP.

1.7.2. **International Product Labels**

1.7.2.1. Product labels must be labeled according to NMDP-identified standards and shall not include any Donor-Identifying Information.

1.7.2.1.1. Notwithstanding other provisions of this SOP, international collection centers and apheresis centers may include specific Donor-Identifying Information, when the facility must do so to comply with its local and/or country-specific regulations regarding product labeling. Information provided in this manner and for this purpose otherwise
remains subject to the requirements and limitations of this SOP.

1.7.2.1.2. In the event a TC receives an international product labeled with Donor-Identifying Information, the TC shall, after verification of the product’s identity and patient information, and to the extent not otherwise prohibited by law or regulation, cover, conceal, or redact such Donor-Identifying Information.

1.7.3. **Research Standards**

1.7.3.1. NMDP is bound by strict standards regarding all research involving Donors and Patients. Participation in research is completely voluntary for each donor and patient.

1.7.3.2. Each donor and patient must sign a consent form to participate in any research study.

1.7.3.3. Donor- or patient-identifying information is prohibited in published research results.

1.7.4. **NMDP Personnel as Donors or Patients**

1.7.4.1. NMDP Personnel may not use NMDP data systems or other means of identifying their Donor or Patient, Donors or Patients of family and friends, or other Donors or Patients with whom NMDP Personnel have no NMDP business involvement.

1.7.5. **Working with the Media**

1.7.5.1. For guidance on what to do when a Donor and/or Recipient is requested for media coverage, refer to the NMDP “Confidentiality Guidelines for Working with the Media,” on the network website.

1.7.6. **Donor Sharing of Information on Social Media**

1.7.6.1. Guidelines for donors seeking to share donation information through social media can be found in the “Guidelines for Social Media Sharing,” on the network website.

1.7.7. **NMDP Network Use of Social Media**

1.7.7.1. Guidance for NMDP Network use of social media can be found in the “Social Media Confidentiality Guidelines for National Marrow Donor Program/Be The Match Network Partners,” on the network website.
1.8. **NMDP Staff Responsibilities for SOP on Donor and Patient Confidentiality**

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

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

1.8.1.2. Accept and record reports of Patient Confidentiality Incidents from NMDP Personnel, the NMDP Network, or others;

1.8.1.3. Compile or supervise compilation of information in support of reporting outlined in § 3 (“Confidentiality Incidents”) of this SOP;

1.8.1.4. Assist in investigation of Confidentiality Incidents, at the request of Regulatory & Quality Assurance and/or other appropriate departments; and

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

1.8.2. The responsibilities of the Manager, Donor Advocacy include, but are not necessarily limited to:

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

1.8.2.2. Accept and record reports of Donor Confidentiality Incidents from NMDP Personnel, the NMDP Network, or others;

1.8.2.3. Accept and address requests for exceptions under the Exception Process for Contacts in the First Year After Transplant, as provided in § 1.6.3.9 of this SOP.

1.8.2.4. Compile or supervise compilation of information in support of reporting outlined in § 3 (“Confidentiality Incidents”) of this SOP;

1.8.2.5. Assist in investigation of Confidentiality Incidents, at the request of Regulatory & Quality Assurance and/or other appropriate departments; and

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

1.8.3. The responsibilities of the leader of Regulatory & Quality Assurance include, but are not necessarily limited to:
1.8.3.1. Administer and manage the NMDP Quality Management System, which stores documentation related to disclosures impacting or potentially impacting confidentiality;

1.8.3.2. Coordinate the investigation for each reported Confidentiality Incident;

1.8.3.3. Coordinate the corrective action/preventive action (CAPA) process for each reported Confidentiality Incident; and

1.8.3.4. Record resolution/outcome of each reported Confidentiality Incident.

1.8.4. The responsibilities of the Human Resources Managers include, but are not necessarily limited to:

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

1.8.4.2. Assist in investigation of Confidentiality Incidents, at the request of Regulatory & Quality Assurance and/or other appropriate departments;

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

1.8.4.4. 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.

1.8.5. The responsibilities of the Vice President, Legal Affairs & Risk Management include, but are not necessarily limited to:

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

1.8.5.2. Assist in investigation of Confidentiality Incidents, if requested by Regulatory & Quality Assurance and/or other departments;

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

1.8.5.4. Evaluate Confidentiality Incidents for reporting to the Chief Executive Officer and the Health Resources & Services Administration and report Confidentiality Incidents, where appropriate.
1.8.6. The responsibilities of other department Senior Vice Presidents, Vice Presidents, Directors, Managers, and/or Supervisors include, but are not necessarily limited to:

1.8.6.1. Assist employees in reporting Confidentiality Incidents;

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

1.8.6.3. With guidance from the appropriate Human Resource Manager, take appropriate disciplinary action toward an offending employee, per provisions set forth in the corrective action/preventive action (CAPA) process procedure, and document activities related to that.

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. Learning & Development 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. Learning & Development 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, at least annually.

2.3.1. Learning & Development shall be responsible for provision of the training and establishing training compliance criteria.

2.3.2. Provider Experience/Provider Network Services, in collaboration with Learning & Development, shall be responsible for confirming that network centers comply with NMDP confidentiality training requirements, for network center staff, where applicable.

3. **Confidentiality Incidents**

3.1. **Internal Reporting of Confidentiality Incidents**

3.1.1. All NMDP Personnel are required to report activities or issues that involve or may involve a Confidentiality Incident.
3.1.2. NMDP Personnel should report such activities or issues in accord with the reporting identified in § 1.8 of this SOP (“NMDP Staff Responsibilities for SOP on Donor and Patient Confidentiality”), for the type of information and Confidentiality Incident at issue.

3.1.3. NMDP Personnel may report Confidentiality Incidents to a supervisor.

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

3.2. **NMDP Network Reporting of Confidentiality Incidents**

3.2.1. NMDP Network members are required to report activities or issues that involve or may involve a Confidentiality Incident.

3.2.2. NMDP Network members should report such activities or issues in accord with the reporting identified in § 1.8 of this SOP (“NMDP Staff Responsibilities for SOP on Donor and Patient Confidentiality”), for the type of information and Confidentiality Incident at issue.

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

3.3. **Investigation and Corrective Actions**

3.3.1. Any report of a possible Confidentiality Incident will be promptly and thoroughly evaluated in accord with this SOP.

3.3.1.1. Each possible Confidentiality Incident shall be preliminarily examined and evaluated based on its known circumstances to determine if it is an actual Confidentiality Incident or is a Confidentiality Concern.

3.3.1.1.1. If it is determined that the Confidentiality Incident involved only unauthorized disclosure of information wholly within NMDP, did not cause and could not have caused a significant injury, and was not intentional, it will be categorized as a Confidentiality Concern in NMDP MasterControl and will be addressed internally. It will not be investigated under § 3.3.2.

3.3.1.1.1. Refer to “Confidential Information SOP Table (A00696)” in assessing each possible Confidentiality Incident, identifying it as an actual
3.3.1.2. Confidentiality Concerns shall, together with Confidentiality Incidents within § 3.3.2.2, be reported to the Chief Executive Office and the Health Resources & Services Administration, in reports containing collected listings with descriptions, on a semi-annual basis.

3.3.2. Except as provided in § 3.3.1 and its subparts, Confidentiality Incidents will be entered into the Quality Management System and investigated and evaluated based on, without limitation, their factual circumstances; the confidentiality policy or procedures at issue; the significance of any injury or potential injury that was, is, or may have been caused by the Confidentiality Incident; and where possible, a determination of the intent or lack of intent in the actions leading to the Confidentiality Incident.

3.3.2.1. Confidentiality Incidents that are determined to have caused or that could have caused a significant injury and/or were intentional shall be reported to the Chief Executive Officer and the Health Resources & Services Administration at completion of the investigation.

3.3.2.2. Confidentiality Incidents that are within § 3.3.2 but are determined not to have caused a significant injury and were not intentional shall be reported to the Chief Executive Officer and the Health Resources & Services Administration, in the reports provided for in § 3.3.1.1.2.

3.3.3. Corrective and/or disciplinary action may be taken, based on the investigation and evaluation.
3.3.3.1. Responsive actions may include, without limitation, the following:

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

3.3.3.1.2. 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.

3.3.3.1.3. 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.”

3.3.3.1.4. In all cases, reporting of the Confidentiality Incident to the Health Resources & Services Administration, where appropriate under the requirements of this SOP.

REFERENCE DOCUMENTS
Not applicable

REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision</th>
<th>Brief Description of Revision</th>
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<tbody>
<tr>
<td>S00339 rev 1</td>
<td>New SOP</td>
</tr>
<tr>
<td>S00339 rev 3</td>
<td>Revisions to permission requirements for Patient Services’ sharing of information regarding Patient contacts, search status, and identification of Transplant Center. Revisions to descriptions of permissible information that can be provided to Donors, prohibiting provision of such information to cord blood Donors.</td>
</tr>
<tr>
<td>Revisions to reflect revised investigation process for breaches involving Confidential Information disclosures limited to internal NMDP staff.</td>
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<tr>
<td>Revision to reflect change of NMDP personnel responsible for contacts regarding post-donation donor/recipient communications.</td>
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<tr>
<td>Addition of reference to social media sharing guidelines for donors.</td>
<td></td>
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<tr>
<td>Revisions for clarification. Added Scope and Responsibilities sections to meet template requirements.</td>
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| S00339 rev 4 | Addition of reference to NMDP email security policies, SOPs, and processes in discussing secure email. |
| --- |
| Revision of information TC may receive in initial stages of search activity, to reflect Traxis data fields and to provide TCs with managing Donor Center for possible matching donors. |
| Identification of Patient information NMDP Donor Center staff and network Donor Center staff may provide to ACs, CCs, or CBBs to confirm product identification and support product distribution/transport. |
| Deletion of repetitive references to legal requirements in SOP content and unneeded general reference to effect of Donor consent. |
| Revision of information that may be disclosed to defined entities (NMDP Biorepository or services providers receiving samples) for use as identifying information. |
| Addition of reference to Network social media guidelines. |
| Revision to require annual training on Confidential Information (Donor/Patient Confidentiality) SOP. |
| Revisions to referenced NMDP department/function titles, personnel titles, and/or document titles. |
| Retitled SOP to specifically identify application to “Unrelated” transplants. |
| Grammatical revisions. |

<p>| S00339 rev 5 (HRSA approval date to be added) | Process changes related to phase-out of the NMDP Service Center Application. |
| --- |
| Internal terminology changes and (1) addition of a definition to replace Confidentiality “Breach” with Confidentiality “Incident” to avoid potential confusion with HIPAA “breach” response requirements; (2) replacement of Confidentiality “Occurrence” with “Concern,” to avoid reporting of confidentiality events in the “occurrence database”; and (3) definition of “Primary Donor |</p>
<table>
<thead>
<tr>
<th>Identifier(s)™ in support of transition to a new donor identification method through implementation of the Global Registration Identifier for Donors (GRID).</th>
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</thead>
<tbody>
<tr>
<td>Revisions to allow sharing of certain Donor availability information with Transplant Centers, at the initial and workup stages, specific to determining availability and collection date (Secs. 1.4.1.2.4, 1.4.1.4.2).</td>
</tr>
<tr>
<td>Revisions to referenced NMDP department/function titles, personnel titles, and/or document titles.</td>
</tr>
<tr>
<td>Grammatical and clarity revisions.</td>
</tr>
</tbody>
</table>

**ADDENDA**

Not applicable