POLICY

POLICY STATEMENT

It is the policy of National Marrow Donor Program® / Be The Match® ("NMDP") that all records at the participating Network centers be retained, regardless of the type/physical form or mediums in accordance with applicable:

1. Federal, state and/or local law and regulations;
2. Statutes of limitation; and
3. Contractual requirements.

All staff at the participating Network centers shall be responsible for ensuring the security, privacy and confidentiality of medical records, as required by law, accrediting agencies, and specific institutional policies.

BUSINESS SECTION/DEPARTMENT

Quality & Regulatory Affairs

PURPOSE

The records of NMDP donors and patients are important assets, and this policy is intended to ensure the most efficient and effective operation of the participating Network centers through implementation of record retention procedures in accordance with applicable local, state and federal legal requirements. Records include those related to donors, recipients, and manufacturing of the collected product that the participating centers possess or control, whether in electronic or paper ("hard copy") form.

Applicable federal and state laws may require the participating Network centers to maintain certain types of records for a specified period or periods of time in addition to accreditation requirements. Of particular note, products under Investigational New Drug (IND) research have unique record retention requirements. For IND research, the U.S. Food and Drug Administration (FDA) requires that sponsors and investigators retain relevant records for two (2) years after a marketing application is approved for the drug or the IND is closed (21 CFR 312.57). Failure to retain the records for those minimum periods could subject the center to penalties and fines, cause a loss of rights, obstruct justice, spoil potential evidence in a lawsuit, place NMDP and the participating center in contempt of court, or be a disadvantage in litigation.

Any uncertainties as to any requirements set forth in this policy or the participating Network center's policies should be communicated to the relevant legal affairs representatives.

SCOPE

This policy applies to all participating Network centers of NMDP.

RELATED DOCUMENTS

1. A00331, *Quality and Regulatory Considerations* (Chapter 20 of Donor Center Manual of Operations)
2. A00422, *Regulatory Matters: Adverse Events, Nonconforming Products and Confidentiality Incidents* (Chapter 17 of Transplant Center Manual of Operations)

DEFINITIONS

Electronic Record(s) means and includes all forms of electronic materials on which any words, phrases, or images are affixed, without limitation including email, word processing documents, electronic forms, spreadsheets, databases, instant messages, calendars, telephone or meeting logs, voice messages, audio recordings, videotapes, motion pictures, slides, photographs, sketches, charts, graphs, SharePoint files, Internet usage files, and information stored in smartphones, PDAs, or similar devices, or removable media (e.g., CDs, DVDs, and flash/“jump”/“thumb” drives).

Record(s) means and refers to all donor and recipient medical records/documents including written, printed, and recorded materials, as well as electronic records.

RESPONSIBILITIES

NMDP participating Network centers shall implement record management practices in accordance with the requirements below:

- Educate staff in understanding sound record management practices, including being able to determine and understand what records should be retained, the length of their retention, and when and how they should be destroyed;
- Ensure that access to confidential records and information is secured;
- Destroy records at expiration of the applicable retention period; and
- Ensure that records are destroyed in a manner that is appropriate for the type of records and information involved.

REQUIREMENTS

1. **All Records**
    a. Retain records for reference, future use, and to meet applicable legal requirements.
    b. Records shall be stored to preserve record legibility and integrity for the entire retention period be protected from accidental or unauthorized access, destruction, or modification and allow retrieval.

2. **All Electronic Records**
    a. The retention requirement for any Electronic Record is based on its content and not its method of delivery.
    b. Retained Electronic Records must meet retention requirements of the participating Network center's institutional backup plan.
3. **Delete/Destroy Records**
    a. Deletion or destruction must be done in accordance with the participating Network center's institutional policy and only when any applicable retention period has expired and the record is no longer necessary.
4. **General Record Requirements for All Participating Centers**
    a. For documents, NMDP is requiring indefinite record retention due to federal regulations related to IND, Institutional Review Board (IRB), and related requirements for open studies.
        i. This policy will be revised should the relevant studies close.
    b. Center shall have secure record storage.
    c. Records shall be created concurrently with the performance of each critical activity. The work performed, the individual performing the work, and when the work was performed shall be identified.
    d. Records shall be legible, indelible, complete, and retrievable in a reasonable period of time.
    e. Records shall be preserved and protected from accidental or unauthorized destruction or modification.
    f. All records and communications relating to patients, recipients, donors or potential donors shall be kept strictly confidential.
    g. Records shall be made available for inspection by authorized individuals.
    h. Relevant to the processes performed at each site, records shall be maintained to ensure the identification and traceability/trackability of each donor cellular therapy product and all related samples from their initial source, through each processing and testing step to their final disposition and from final disposition, through each processing and testing step to the initial source.
5. **Computerized Record Requirements**
    a. Center shall maintain the authenticity, integrity and confidentiality of all records, access to which is limited to authorized individuals.
    b. Center shall have technical and operational support for information systems management.
    c. Records shall be maintained in a way to ensure their integrity and preservation for the duration of the defined retention period and be retrievable.
    d. Before destruction of original records, uploaded copies of such records shall be verified as a "true copy" (legible, indelible, and complete).
    e. If not using NMDP-developed computer systems, centers shall document the following:
        i. Validation of system functionality (hardware, software and database).
        ii. Validation and monitoring of data integrity.

f. All centers shall document the following:
    i. Installation and upgrades of the system.
    ii. Training and continuing competency of personnel.
    iii. Policies and procedures for system maintenance and operations.
    iv. Ongoing backup procedures.
    v. Documented and tested procedures for data restoration.
    vi. Offsite storage of electronic data records.
g. Computer records shall be protected to enable their accurate and ready retrieval throughout the period of required record retention.
h. Center shall have an alternative system that permits continuous operation in the event that computerized data are not available.

6. **Retention of Records – Indefinite**
    a. The following Donor Center records pertaining to donors who have been activated for workup shall be retained indefinitely:
        i. Consent documents for all stages of the search process
        ii. Health history screenings, including reasons for permanent or temporary deferral
        iii. Infectious disease testing and/or laboratory results
        iv. Documentation of abnormal findings and the notification/counseling of the relevant parties
        v. Records of adverse reactions and post donation complications and recovery
        vi. All source documents
            1. NMDP considers any form that is completed for NMDP containing requested information from another document as a source document.
    b. Apheresis and Collection Center records that shall be retained indefinitely:
        i. Consent documents from donors for the collection of products for allogeneic use
        ii. Screening and testing records
        iii. Records pertaining to collection, processing, labeling, packaging, storage, distribution, and final disposition of collected product
            1. Records pertaining to qualification, monitoring and use of reagents, supplies, and materials shall be traceable to collected product
            2. Records pertaining to qualification, calibration, maintenance, monitoring, and use of equipment shall be traceable to collected product
            3. Records pertaining to the traceability and tracking of all aspects of the manufacture of the HPC product performed at the site with the exception of facility cleaning and sanitation records, which are retained minimally for 3 years
        iv. Records of adverse reactions and post-donation complications, treatment interventions and recovery

c. Transplant Center recipient records that shall be retained indefinitely:
    i. Informed consent documents related to NMDP-facilitated cellular therapy products
    ii. For recipient formal (activated) search activity, results of donor and recipient HLA typing and other test results at the Transplant Center, including the identification numbers of participating donor(s)
        1. A donor collection must have been completed or donor must have started Filgrastim or other biosimilars to comply with 6.c.ii.
        2. If a cord blood product, the product would have to be infused to comply with 6.c.ii.
    iii. Records pertaining to any NMDP-facilitated search including:
        1. The identification numbers of participating donor(s)/cord blood unit(s)
        2. Abnormal donor/cord blood unit or recipient findings and notification/counseling of relevant parties
        3. Product testing results, including ABO/Rh typing and microbial cultures
    iv. Records related to adverse events associated with NMDP-facilitated cellular therapy products
    v. Records related to final disposition of NMDP-facilitated cellular therapy products

7. **Retention of Records – Finite (retain for a minimum of three years)**
    a. Donor center donor records pertaining to individuals who have been deleted from the Be The Match Registry® and had never been activated for a formalized search
    b. Records of donors who have been activated but deleted or deferred from the Be The Match Registry prior to signing a search stage consent form or initiation of a health history questionnaire
8. **Retention of Records – Donor Center Transferred Donors**
    a. Records of all transferred donors shall be forwarded to the receiving donor center
    b. Copies of records pertaining to transferred donors who did not donate may be discarded by the transferring center after three years
9. **Retention of Records – Donor Center Closing Centers**
    a. Any center that ceases affiliation with the NMDP shall make provisions for maintenance or transfer of records as approved by the NMDP.

REFERENCES

FDA requirements: 21 C.F.R. § 56.115; 21] C.F.R. § 211.198; 21 C.F.R. § 312.57(c); 21 C.F.R. § 312.62(c); 21 C.F.R. § 1271.3(c)(m); 21 C.F.R. § 1271.55(d); 21 C.F.R. § 1271.270; 21 C.F.R. § 1271.320

U.S. Department of Health & Human Services (HHS) requirements: 45 C.F.R. § 46.115

REVISION HISTORY

Revision	Brief Description of Revision
P00143 rev. 1	New Policy

ADDENDA

Not applicable.