

National Marrow Donor Program®
POLICY

**Policy for Cord Blood Bank Qualification and Renewal for the NMDP's
IND for Access and Distribution of Unlicensed Cord Blood Units**

Business Section/Department: Operations

It is the policy of the National Marrow Donor Program (NMDP) to establish formal relationships with cord blood banks and registries worldwide that may contribute to and participate in the mission of the NMDP.

The NMDP sponsors an FDA-approved Investigational New Drug (IND) application (BB IND 7555). This IND allows the NMDP to facilitate the access to unlicensed cryopreserved allogeneic placental/umbilical cord blood units for unrelated recipients in the U.S. The IND supports cord blood units, also referenced as HPC(CB), from both U.S. and non-U.S. cord blood banks that are not licensed in accordance with 21 CFR 601.

Cord blood banks that wish to provide their unlicensed HPC(CB) to U.S. recipients under the NMDP IND must meet IND qualification requirements as defined by the NMDP and approved by the FDA, in addition to meeting applicable regulations within their own country. Specific requirements for qualification are listed within the IND. Published separately and available publicly, the NMDP Investigational New Drug (IND) Supplier Requirements for Cord Blood Banks support the NMDP IND-defined requirements.

Relationships with qualified cord blood banks (or their respective registries) are established and maintained through a standard set of processes that include supplier requirements, application submission and review, contractual agreements, and annual compliance monitoring.

Purpose

The *Policy for Cord Blood Bank Qualification in the NMDP's IND for Access and Distribution of Unlicensed Cord Blood Units* seeks to ensure that cord blood banks providing unlicensed HPC(CB) facilitated by the NMDP for intended transplantation in the U.S. meet and maintain relevant requirements, including those set forth within BB-IND 7555, NMDP policies and procedures, and any applicable laws or regulations. All cord blood banks that wish to involve the NMDP in facilitating the availability of their HPC(CB) must be initially approved by the NMDP and demonstrate ongoing compliance with requirements on an annual basis.

NMDP, in its sole discretion, may agree to work with a cord blood bank to the extent set forth herein, so long as the cord blood bank meets the applicable requirements of this Policy.

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Scope

The policy affects potential and existing cord blood banks that wish to provide unlicensed HPC(CB) to recipients in the U.S. This policy also affects NMDP staff involved in the initial and annual qualification and review of these banks.

Definitions

Cord Blood Bank (bank): An institution that manages an inventory of cryopreserved unrelated donor HPC(CB).

Distribution: Any HPC(CB) unit facilitated by the NMDP must be distributed in the U.S. under an FDA-accepted Investigational New Drug (IND) application or Biologics License Application (BLA). If a cord blood bank (U.S. or non-U.S.) wishes to provide unlicensed HPC(CB) to U.S. patients through the NMDP, the bank must qualify under the NMDP's IND, or another FDA-approved IND.

Affiliation with the NMDP:

There are two categories of cord blood bank participation with the NMDP:

- Member cord blood banks
- Affiliated cord blood banks. This category can be further differentiated as:
 - Affiliated Listing banks
 - Affiliated Non-Listing banks

Qualification Team (QT): A team comprised of NMDP staff members with expertise in cord blood operations, regulatory issues, and network membership. This team reviews the completed *NMDP Investigational New Drug (IND) Qualification Form for Cord Blood Banks* (an application form) from banks that wish to provide unlicensed HPC(CB) to recipients in the U.S. via the NMDP IND.

Bank Categories

All banks must submit documentation initially and on an ongoing (annual) basis to demonstrate their compliance with applicable NMDP requirements.

1. Member cord blood banks must meet *NMDP Investigational New Drug (IND) Supplier Requirements for Cord Blood Banks*, be accredited by AABB or NetCord-FACT, meet *NMDP Member Cord Blood Bank Participation Criteria* and adhere to *NMDP Standards and NMDP Current Inventory Requirements for New Cord Blood Units*. They must submit the associated *NMDP Investigational New Drug (IND) Qualification Form and an NMDP Application to participate as a Member Cord Blood Bank*. Applicant banks must also successfully pass an initial on-site audit conducted by NMDP staff.

Member banks provide HLA and other relevant information about their HPC(CB) to the NMDP for inclusion (listing) in the Be The Match Registry using an NMDP-provided software application. These HPC(CB) are identified on the "up-front" search result listings to transplant centers and registries with an NMDP-assigned ID number. Continued compliance in meeting *NMDP Investigational New Drug (IND)*

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Supplier Requirements for Cord Blood Banks, NMDP Member Cord Blood Bank Participation Criteria, and NMDP Current Inventory Requirements for New Cord Blood Units is assessed annually.

Benefits for member banks:

- Inclusion of its qualified HPC(CB) in the “up-front” search report generated for NMDP Network Transplant Centers and Cooperative Registries.
- NMDP’s facilitation of testing and importation of unlicensed HPC(CB) for U.S. patients via the NMDP’s FDA-approved IND.
- Eligible for invitation for one representative to participate as a voting member of the NMDP Cord Blood Advisory Group.
- Eligibility to attend the NMDP Council Meeting under the terms of the NMDP Council Meeting Grant Program.
- Eligible to participate in NMDP special programs, initiatives and pilot programs
- Access to NMDP-owned equipment (for example dry shippers and data loggers)
- No-cost access to educational materials and documents produced by the NMDP.
- No-cost access to the NMDP Network website.
- No-cost use of NMDP software applications used to list HPC(CB) in the Be The Match Registry.

2. Affiliated Listing Banks must meet *NMDP Investigational (IND) Supplier Requirements for Cord Blood Banks* via submission of an acceptable *NMDP Investigational New Drug (IND) Qualification Form for Cord Blood Banks*. The bank must also be accredited by AABB or NetCord-FACT for cord blood banking, or be inspected by a local or national competent authority. They must comply with *NMDP Current Inventory Requirements for New Cord Blood Units*. A minimum of 500 units are required for consideration. Listing banks provide HLA and other relevant information about their HPC(CB) to the NMDP for inclusion (listing) in the Be The Match Registry “up-front” search report using an NMDP-provided software application or customized electronic mechanism. These HPC(CB) are identified on search result listings to transplant centers and registries with either an NMDP-assigned ID number or a local ID, depending on the mechanism used for uploading the data.

Banks must participate as an Affiliated Non-Listing Bank for at least six months before requesting to become a Affiliated Listing Bank.

Benefits for Listing banks:

- Inclusion of its qualified HPC(CB) in the “up-front” search reports generated for NMDP Network Transplant Centers and Cooperative Registries.
- NMDP’s facilitation of testing and importation of unlicensed HPC(CB) for U.S. patients via the NMDP’s FDA-approved IND.
- No-cost access to the NMDP Network website.
- Use of NMDP software applications used to list HPC(CB) in the Be The Match Registry.

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Continued compliance in meeting *NMDP Investigational New Drug (IND) Supplier Requirements for Cord Blood Banks* and *NMDP Current Inventory Criteria for New Cord Blood Units* is assessed annually.

- 3. Affiliated Non-Listing Banks** must meet *NMDP Investigational New Drug (IND) Supplier Requirements for Cord Blood Banks* via submission of an acceptable *NMDP Investigational New Drug (IND) Qualification Form for Cord Blood Banks*. The bank must have an inventory of at least 100 IND-qualified units.

HPC(CB) IDs are not included in the Be The Match Registry “up-front” search reports. These HPC(CB) may be found through automated searching mechanisms such as the Bone Marrow Donors Worldwide (BMDW) or European Marrow Donor Information System (EMDIS), or may be found through individual fax or e-mail requests to a Cord Blood Bank or associated Registry. Some banks operate under the umbrella of a registry (typically a national registry), for which all communication, contracting, invoicing and payment occurs via the registry. Other banks have a direct relationship with the NMDP.

Affiliated Non-Listing banks must participate in this category for at least six months before requesting to become an Affiliated Listing Bank or Member Bank.

Benefits for Affiliated Non-Listing banks:

- NMDP’s facilitation of testing and importation of unlicensed HPC(CB) for U.S. patients via the NMDP’s FDA-approved IND.
- If IND-Qualified banks submit data to BMDW or use EMDIS, HPC(CB) will be included in specialized NMDP search lists (BMDW cord list, Cooperative Registry Cord list) available to NMDP network transplant center and Cooperative Registries in Traxis®. HPC(CB) appear on these specialized lists with a bank/registry-provided local ID number.

CBB Qualification and Facilitation Summary

A bank in any of these categories may hold a BLA to distribute licensed HPC(CB) or sponsor their own FDA-approved IND (in addition to qualifying under the NMDP’s IND) through which the NMDP may facilitate shipment of their HPC(CB).

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Affiliation Category	NMDP IND Qualified*	NMDP Member CBB Participation Criteria	Minimum Inventory Size of 500 units	NMDP Current Inventory Requirements for New Cord Blood Units	AABB or NetCord-FACT Accredited	Adhere to FDA/CFR 1271 Screening and Testing requirements	Working towards FDA Licensure
Member CBB	Y	Y	Y	Y**	Y	Y	Y
Affiliated Listing CBB	Y	N	Y	Y**	N***	N	N
Affiliated Non-Listing CBB	Y	N	N	N	N***	N	N

* NMDP may determine, on a case-by-case basis, that a bank's FDA-approved IND may be substituted in lieu of qualification under the NMDP's IND. If a bank's entire inventory is FDA-licensed, the requirement to qualify under NMDP's IND may be waived.

**Note: NMDP Current Inventory Requirements differ for Member vs. Affiliated banks.

*** At a minimum, the bank must be inspected by a local or national competent authority per NMDP IND requirements.

Qualification and Renewal

Initial IND Qualification forms for all bank categories are reviewed by the Cord Blood Qualification Team. The Qualification Team will meet on an as-needed basis, as new requests for qualification are received. Final approvals are provided by the Principal Investigator of BB-IND 7555.

Initial applications to participate as a Member cord blood bank are reviewed by NMDP staff representing Regulatory Compliance, Cord Blood Operations and Case Management. Recommendations for approval are provided by the NMDP Membership Review Committee, followed by either the NMDP Executive Committee or Board of Directors.

Audits performed at applicant Member cord blood banks will be performed by representatives of Regulatory Compliance and Cord Blood Operations.

Affiliated Non-Listing banks that wish to become a Listing bank or Member bank must participate as a Affiliated Non-Listing bank for at least six months before NMDP will consider a change to their status. Affiliated Listing Banks must be actively collecting units, and must have at least 500 units that meet current *NMDP Current Inventory Requirements for New Cord Blood Units*.

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Ongoing, annual compliance of IND Supplier Requirements (for all bank categories) and Participation Criteria (for Member cord blood banks) will be performed by NMDP staff on an annual basis. Continued compliance with *NMDP Current Inventory Requirements for New Cord Blood Units* will also be assessed for Member Banks and Affiliated Listing Banks.

Non-compliant banks will be brought to the attention of the Principal Investigator of BB-IND 7555 and the Membership Review Committee.

Responsibilities

The Vice President and Senior Medical Director of the NMDP, as Principal Investigator of BB-IND 7555, is responsible for oversight of policies and procedures that affect the qualification and continued compliance of cord blood banks.

The Senior Vice President of Operations is responsible for the oversight of staff in Cord Blood Operations and Case Management for tasks relevant to qualification and renewal.

References / Related Documents

BB-IND 7555	A Centralized Cord Blood Registry to Facilitate Allogeneic, Unrelated Donor Umbilical Cord Blood Transplantation
A00498	NMDP Investigational New Drug (IND) Supplier Requirements for Cord Blood Banks
F00767	NMDP Investigational New Drug (IND) Qualification Form for Cord Blood Banks
A00092	NMDP Member Cord Blood Bank Participation Criteria
A00597	NMDP Current Inventory Requirements for New Cord Blood Units
F00142	Application for Participation as a Member Cord Blood Bank