



NATIONAL MARROW DONOR PROGRAM
Investigational New Drug (IND)
Qualification Form for Cord Blood Bank

This form must be signed, submitted, and approved by the NMDP before any units can be imported into the U.S., or shipped within the U.S., due to U.S. Cord Blood Licensure requirements that became effective October 20, 2011.

GENERAL CORD BLOOD BANK (CBB) DESCRIPTION

Cord Blood Bank Legal Name: _____

Cord Blood Bank Public Name: _____

Cord Blood Bank Address: _____

1. Is your CBB a member of a national registry? yes no
If yes, specify which registry: _____
2. What year did your CBB collect/process its first cord blood unit (CBU)? _____
3. What year did your CBB provide its first unit for transplantation? _____
4. How many units are currently in your CBB's inventory? _____
5. Is your CBB currently collecting new inventory? yes no
6. Complete the chart below to list the number of units that have been provided for transplantation in the past three years.

Calendar Year	# Domestically	# To Another Country

7. Where does your CBB list its units (check all that apply)
Within a national registry
BMDW
Other: _____

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PERSONNEL

8. CBB Medical Director

Name: _____ Degree: _____

Title: _____

Address: _____

Phone: _____

Fax: _____ Email: _____

Licensed in your country? License number: _____

Enclose CV

9. CBB Coordinator (contact person for NMDP operations)

Name: _____ Degree: _____

Title: _____

Address: _____

Phone: _____

Fax: _____ Email: _____

Is coordinator proficient in English? Yes No

10. Backup CBB Coordinator

Name: _____ Degree: _____

Title: _____

Address: _____

Phone: _____

Fax: _____ Email: _____

Is backup coordinator proficient in English? Yes No

11. CBB Laboratory (Processing Facility) Director (if different from CBB Medical Director)

Name: _____ Degree: _____

Title: _____

Address: _____

Phone: _____

Fax: _____ Email: _____

Enclose CV

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12. Does your CBB currently document and define the qualifications, responsibilities, training, continuing education, and continued competency of its staff? yes no
13. Does your CBB have a process to document training for individuals who collect cord blood units? yes no

MATERNAL DONOR CONSENT/SCREENING/TESTING

14. Have all maternal donors always signed a consent form at (or near) the time of cord blood collection that specified the unit would be collected, tested, stored and intended for use in unrelated donor transplantation? yes no

15. Have maternal donors ever been:
 - Coerced (forced) to donate cord blood units? yes no
 - Paid to donate cord blood units? yes no
 - Charged fees for any aspect of the collection, donation, or storage of the unit? yes no

16. Is a maternal donor questionnaire currently completed (within six months prior to collection or one month after) to assess high risk behaviors?
 yes no

Enclose copy of questionnaire and associated criteria used to list or defer/discard the unit
(both documents must be in English)

17. Is a family medical health history (infant's mother, father and siblings) currently completed (within six months prior to collection or one month after)?
 yes no

Enclose copy of questionnaire and associated criteria used to list or defer/discard the unit
(both documents must be in English)

18. Is a review of readily available delivery/medical records currently conducted for evidence of relevant communicable disease and is this review documented? yes no

19. Has maternal infectious disease marker (IDM) testing always been performed on a sample collected from the mother within (before or after) seven days of donation? yes no

20. Using the list below, indicate which IDM testing of the maternal donor and cord blood unit is **currently** performed. Note: All tests specified are not required for current and previous inventory. See next question for minimum required tests.

Test	Maternal Testing	Unit Testing
Hepatitis B Surface Antigen		
Antibody to Hepatitis B core		
HBV NAT		
Antibody to Hepatitis C		
HCV NAT		
Antibodies to HIV 1 and 2		
Antibodies to HIV 1 and 2 + O		
HIV p24 antigen		

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HIV NAT		
Antibodies to HTLV I/II		
CMV Antibody Total		
CMV Antibody – Other:		
Syphilis		
West Nile Virus NAT		
T. Cruzi Antibody (Chagas Disease)		
EBV Antibody		
Toxoplasmosis Antibody		
Other:		

21. Has maternal IDM testing (for all units in your inventory) always included testing for:

- Antibody to HIV 1 /2 yes no
- HIV antigen (p24 or NAT) yes no
- Hepatitis B surface antigen yes no
- Hepatitis C Antibody yes no

NOTE: These tests are required for all CBU shipments facilitated through the NMDP IND.

OPERATIONS (COLLECTION, PROCESSING, CRYOPRESERVATION AND STORAGE)

22. Do all cord blood units and their related records (including the medical history of the mother and family, maternal testing, unit testing; and processing, cryopreservation and storage records) currently undergo review by a physician (or designee) prior to making the unit available for listing? yes no

23. Are the lot numbers of all materials, and reagents used in the manufacturing of the unit currently recorded? yes no

24. Is the equipment used in the manufacturing of the unit currently recorded?
 yes no

25. Have all of the collection and processing bags used by your CBB always been approved for human use? yes no

26. Have all of the anticoagulants, diluents, media and cryoprotectants (listed in the next four questions) used by your CBB always been approved for human use? yes no

NOTE: This does not include DMSO.

If no, specify which are not approved: _____

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27. Indicate which of the following anticoagulants are used (check all that apply)

Anticoagulant	Used in the past	Used currently
Heparin		
Citrate Phosphate Dextrose Adenine Solution		
Citrate Phosphate Dextrose Solution (CPD)		
Acid Citrate Dextrose (ACD)		
Other(s):		

28. Indicate which of the following diluents are used during ex-utero collection (check all that apply)

Diluents	Used in the past	Used currently
Sodium Chloride 0.9%		
Dextrose 5%		
Other(s):		

29. Indicate which media are used (check all that apply)

Media/Methods	Used in the past	Used currently
Hydroxyethyl Starch		
Dextran		
Prepacyte®-CB		
Other(s):		

30. Indicate which cryoprotectants are used during cryopreservation (check all that apply)

Cryoprotectants	Used in the past	Used currently
DMSO		
Dextran (used in conjunction with DMSO)		
Glycerol		
Human Albumin		
Plasmalyte		
Others):		

31. Has your CBB always tracked the product from the donor to the patient and from the patient to the donor? yes no

32. What is the maximum time allowed (in hours) from unit collection to cryopreservation?

Time Allowed	Used in the past	Used currently
Less than 48 hours		
Less than 72 hours		
Other(s):		

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33. Have any units ever been stored > -135° C? yes no
34. When did your CBB adopt the storage temperature of ≤ -150° C? month/year _____
35. Is an electronic temperature alarm monitoring system currently in place? yes no

36. Describe the method(s) used to process units (check all that apply)

Methods	Used in the past	Used currently
Red Cell Depletion Only (RBC reduced)		
Plasma and RBC Reduced		
Volume Reduction Only (plasma reduced)		
Density Separation (density enriched)		
None		
Other(s):		

37. Indicate current long-term storage methods:

Liquid LN2

Vapor LN2

38. Indicate the type of container used to store the units (check all that apply)

Container	Used in the past	Used currently
Cryobags		
Other(s):		

39. Describe the freezing method (check all that apply)

Freezing Method	Used in the past	Used currently
Manual, "Dump" freezing		
Controlled rate freezing		
Other(s):		

40. Has your CBB ever stored CBUs with non-human sources of blood, blood components or tissues? yes no

41. How does your CBB currently prevent potential transmission of infectious disease agents in untested CBUs to units that have been qualified for release? (answer all)

- | | | |
|--|-----|----|
| a. Units are stored with overwrap | yes | no |
| b. Untested units are stored in vapor phase | yes | no |
| c. Untested units are stored in separate freezer | yes | no |
| d. Other, describe: _____ | yes | no |

If there is a different process for CBUs with confirmed positive infectious disease results (except CMV), describe: _____

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42. Provide the name of the laboratory that performs initial HLA typing on your units:

Enclose a copy of HLA lab accreditation (such as EFI, ASHI, CAP, or other) — include current certification letter or document verifying HLA accreditation.

CORD BLOOD UNIT TESTING

43. Indicate microbial tests that have been or are currently performed on all units.

Sterility Cultures	Used in the past	Used currently
Bacterial culture (required for all units)		
Fungal culture (if all units were not tested, indicate date fungal testing was implemented): _____		

44. Has your CBB ever stored any units available for transplant that had a positive microbial test?
yes no

If yes, specify: _____

NOTE: NMDP will not distribute units that have tested positive for infectious agents.

45. a. Is hemoglobinopathy testing currently performed on each cord blood unit/infant donor before the unit is listed? yes no

If testing is performed, indicate if the unit is deferred / rejected if the results are positive.

Test	No, not tested	Yes, tested & CBU deferred if positive	Yes, tested & CBU not deferred if positive
Sickle cell trait (heterozygous)			
Sickle cell disease			
Thalassemia trait			
Thalassemia disease			
Severe α thalassemia disease			

- b. If testing is not routinely performed at time of CBU processing, is a sample available for testing upon request? yes no
- c. If testing is currently not performed, is the mother questioned specifically about her family history of:
- Sickle cell disease yes no
- Thalassemia yes no

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46. Are the laboratories that currently perform testing (ABO/Rh typing, infectious disease marker testing, nucleated cell counts, sterility testing) on your maternal donor and/or cord blood units licensed, accredited, or authorized to operate by a competent national authority?

yes no

47. U.S. transplant centers are required to have HLA-A, B and DRB1 confirmatory/verification typing of the unit performed at an EFI, ASHI or CAP-accredited HLA laboratory. Can your CBB arrange for confirmatory/verification typing to be done at an accredited laboratory?

yes no

If yes, provide the name of the HLA laboratory: _____

Enclose a copy of HLA lab accreditation—include current certification letter or document verifying HLA accreditation.

If no, confirm that your CBB will ship a contiguous segment or other sample to an HLA laboratory designated by the NMDP in the U.S., if requested by the NMDP.

yes no

48. Does your CBB currently provide a cord blood unit report(s) that includes at least the following?

Unique identifier	yes	no
HLA typing	yes	no
ABO/Rh type	yes	no
Infant date of birth or CBU collection	yes	no
Infant gender	yes	no
Microbial testing results	yes	no
Volume (mL)	yes	no
Maternal infectious disease marker	yes	no

Enclose a copy of cord blood unit report(s) in English

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PROCEDURES

49. Indicate in the chart below whether your CBB currently has one or more procedures or documents (followed by your personnel) that describe the following activities.

NOTE: A specific procedure is not required for each item listed below, as long as these topics are addressed overall in some way in the CBB procedures or documents.

NOTE: NMDP is not requesting a copy of your procedures.

PROCEDURE	YES	NO	COMMENTS
Administrative Processes			
Contracts or agreements (examples: collection sites, labs, suppliers)			
Emergency back-up for critical functions (examples: computer, testing, storage)			
Confidentiality requirements			
Collection Processes			
Qualification of collection facilities			
Qualification of collection personnel / training			
Equipment Management			
Preventive maintenance and calibration requirements and frequency			
Instructions for use of equipment			
Equipment qualification			
Facility Management			
Sanitation, cleaning, environmental			
Handling of waste			
Space requirements and security / access			
Supplies / Materials Management			
Supplies / materials receipt, inspection, quarantine and release for use			
Acceptance criteria for use			
Temperature requirements / monitoring, as needed (example: reagents, test kits, etc)			
Donor Qualification / Suitability			
Consent process			
Maternal medical and high risk behavior screening requirements			
Family medical history requirements			
Infectious disease testing profile, sample collection / timing and acceptability criteria			
Delivery collection and acceptability criteria			
Interpretation of medical and high risk behavior, delivery and testing information			
Medical director review of donor suitability			

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PROCEDURE	YES	NO	COMMENTS
Product Processing / Suitability			
Transport time and temperature requirements of unprocessed cord blood			
Unit receipt and acceptability criteria			
Processing time and temperature			
Processing methodology			
Sterility culture methodology and acceptability criteria			
Aliquot collection and storage requirements (examples: samples, attached segments)			
Product testing and acceptance criteria (examples: TNC, CD34+, HLA)			
Product freezing methodology			
Product storage temperature requirements and temperature monitoring during storage			
Review of product suitability / criteria for release of product to available inventory			
Storage of units untested for IDMs or with a positive IDM to protect against transfer of potentially infectious agents to qualified inventory			
Labeling and warning labels / statements			
Initial product labeling requirements when product stored			
Final product labeling requirements when released to ship			
Transportation and Shipment			
Unprocessed cord blood transport container validation requirements and testing			
Cord blood dry shipper validation requirements and testing			
Dry shipper charging and preparation for shipment			
CBU release specifications to ship			
Shipment arrangements / couriers			
Packaging CBU for shipment			
Accompanying instructions requirements for shipment and unit			
Final product disposition (where it was shipped and recipient ID)			
Policy for conditions when or if unused cryopreserved units can be returned to CBB inventory.			

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PROCEDURE	YES	NO	COMMENTS
Training Process			
Staff qualification; procedure / task training and documentation requirements			
Documents Process			
Procedure / forms development, review and approval system			
Procedure / forms implementation, archive and storage system			
Quality Systems			
Complaint / incident system (to document product and service problems and resolution)			
Corrective action system			
Internal audit requirements and schedule			
System for reporting product deviations or recipient serious adverse events			
Quality Plan			
Records Management			
Process for creation, modification, correction, review of, and access to records			
Records retention (storage) criteria and timeframes defined			
System to store records on-site and/or off-site and records retrieval			
Electronic back-up for computerized records, if applicable			

50. Current Records:

- a. Are records of each manufacturing step created at the time the activity is performed?
yes no
- b. Do records include the type of task performed, the identity of the individual performing the task, and when the task was performed? yes no
- c. Are records legible (readable), indelible (permanent), complete, kept indefinitely (forever) and retrievable (able to find) in a reasonable period of time?
yes no

51. Will your CBB report product deviations and recipient serious adverse events (that involve cord blood units under the NMDP IND) to the NMDP? yes no

NOTE: The NMDP will report these events to the WMDA SEAR/SPEAR database.

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LABELING

52. Does your CBB's current label affixed to the cord blood unit include, at a minimum?
- A unique product identifier yes no
 - Proper name of the product as defined in the Circular of Information (COI) or equivalent yes no
53. Is the name and address of the CBU manufacturer and the storage temperature information affixed to the current CBU label, or included in accompanying records? yes no
- Enclose sample (or photo) of label affixed to the unit. If not in English, enclose a translation.
- Enclose a copy of all accompanying records/paperwork sent with the unit.
54. Are all labels affixed to CBUs (including those in storage) in English? If not, will an English translation be sent with the CBU? yes no
55. NMDP will provide your CBB/registry with the paperwork required to import into the U.S. Verify that your CBB will use this information to accompany the CBU at the time of shipment. yes no

SHIPPING

56. Is the cord blood label and associated paperwork reviewed by two individuals at the CBB (or one individual and a validated electronic equivalent) to verify that the information is complete and correct at the time the unit is shipped? yes no
57. Are dry shippers validated to ensure they maintain a temperature of $\leq -150^{\circ}\text{C}$ at least 48 hours beyond the expected arrival time at the receiving facility? yes no
58. Do all dry shippers used by your CBB contain an electronic temperature data logger? yes no
59. Are the contents of dry shippers limited to one CBU? yes no
60. Provide the name of the shipping company that is used to ship units from your CBB to the U.S. You may indicate that your national registry makes these arrangements.
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ACCREDITATIONS/COMPLIANCE WITH OTHER AGENCIES

61. Are there government regulations regarding cord blood banking in your country? yes no

62. Indicate organization(s) that oversee (license, accredit and/or certify) your CBB operations, and provide on-site inspection information in the table below.

Organization	Oversee CBB's operations? Y/N	On-site inspection? Y/N	Frequency (e.g. every year)	Last inspection date
NetCord-FACT				
AABB				
ISO (specify):				
National Donor Registry				
Local/National Government Agency:				
Other:				
Other:				

Enclose copy of license, accreditation or certification from organization(s)

63. Has your CBB been placed on any warning, probation or suspension in the past two years?
yes no

If yes, enclose a description.

ADMINISTRATION

64. Verify that your CBB (or its parent organization or national registry) has agreements in place with every entity that performs any step in the cord blood unit manufacturing process.
yes no

Manufacturing means recovery, processing, storage, labeling, packaging and/or distribution of the unit.


65. Verify that your CBB (or its parent organization or national registry) maintains professional and general liability insurance coverage. This coverage may be privately held, or provided by your national government. yes no

66. The NMDP is required by federal law to obtain your institution's tax information and verification for payments the NMDP will send to your center. Please complete the following forms: 1) The enclosed U.S. Internal Revenue Service (IRS) Form W-9 for all U.S. CBBs. 2) The enclosed U.S. Internal Revenue Service (IRS) Form W-8 for all non-U.S. CBBs. The purpose of these forms is to provide NMDP with your correct taxpayer identification number (TIN) and tax reporting status. If you have questions on how to complete the form, please email nmdpapops@nmdp.org.

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REQUIRED ATTACHMENT CHECKLIST

Ensure the following attachments are enclosed with qualification form submission:

Attachment	Refer to Question #	
Medical Director CV	8	
Laboratory Director CV (if different from Medical Director)	11	
Maternal Donor Risk Questionnaire (MRQ)	16	
Bank Action Form or “tool” to assess if cord blood unit is acceptable based on Maternal Donor Questionnaire (Note: not required to enclose if deferral reasons specified in maternal donor questionnaire document)	16	
Infant’s Family Medical History Questionnaire, if performed	17	
Bank Action Form or “tool” to assess if cord blood unit is acceptable based on Infant Family Questionnaire (Note: not required to enclose if deferral reasons specified in family medical history questionnaire document)	17	
HLA laboratory accreditation (e.g. EFI or ASHI) for laboratory that performs initial HLA typing	42	
HLA laboratory accreditation (e.g. EFI or ASHI) for laboratory that performs confirmatory/verification typing	47	
Cord Blood Unit Report	48	
Sample label affixed to cord blood unit	53	
Sample of accompanying paperwork sent with cord blood unit	53	
Copy of license, accreditation or authorization from organization(s) that oversee (authorize, license, accredit and/or inspect) CBB operations in your country	62	
Description of warning, probation or suspension findings from accrediting organization (if applicable)	63	
IRS form W-8 or W-9	65	



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I verify that the information contained in this IND Qualification Form is accurate.

Name (print): _____

Signature/stamp: _____

Title: _____

Date: _____

Submit this form and attachments to
NMDP Cord Blood Bank Liaisons at cordliaisons@nmdp.org

Cord Blood Banks affiliated with a national registry: Submit to your registry. They will submit to NMDP on your behalf.

Comments or Suggestions:
