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PRINT

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

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	☐	☐

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: _____

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
Hydroxyethel 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):	☐	☐

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: _____

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

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

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.	☐	☐	

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.

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 ≤ -150° 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.

    _____

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:

_____