

CORD BLOOD TRANSPLANTATION STUDY

**CBU EXCLUSION AND QUARANTINE RELEASE FORM**

**Bar Code Label**

(Any answer of "Yes" indicates exclusion)

**1. Informed Consent and Maternal/Infant Demographics**

a. Lack of confirmation of signed and witnessed informed consent 1  Yes 2  No

Is the following information missing from the Volunteer Cord Blood Donor Information Form?

b. Mother's name 1  Yes 2  No

c. Mother's hospital ID number 1  Yes 2  No

d. Mother's home address 1  Yes 2  No

e. Infant ID number 1  Yes 2  No

f. Delivery staff or Cord Blood Collector verification 1  Yes 2  No

g. CRN and/or Phlebotomist verification 1  Yes 2  No

**2. Cord Blood Collection/Processing/Freezing**

a. Missing or improper barcode label on collection bag 1  Yes 2  No

b. Damaged or leaking cord blood collection bag or storage temperature exceeds limits 1  Yes 2  No

c. Volume < 40 ml or volume 40 - 59 ml and insufficient cell count 1  Yes 2  No

d. Recovery < 60% viable nucleated cells and <  $6 \times 10^8$  viable nucleated cells and < 80% viable mononuclear cells (if performed) 1  Yes 2  No

e. Cord blood cells processed > 48 hours after collection 1  Yes 2  No

f. Other collection/processing/freezing problems 1  Yes 2  No  
Specify: \_\_\_\_\_

**3. Family/Maternal/Perinatal Medical/Social History**

*Maternal and First Degree Family Medical History*

a. Cancer (other than basal or squamous cell skin cancers) 1  Yes 2  No

b. Other reason not approved for donation 1  Yes 2  No  
If yes, specify: \_\_\_\_\_

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*Maternal and Extended Family Medical History*

- c. Blood disorder 1  Yes 2  No
- d. Heritable form of immunodeficiency 1  Yes 2  No
- e. Heritable form of coagulopathy 1  Yes 2  No
- f. Metabolic/storage disease 1  Yes 2  No
- g. Other reason not approved for donation 1  Yes 2  No  
*If yes, specify:* \_\_\_\_\_

*Maternal History of Specific Infectious Diseases*

- h. Yellow jaundice, liver disease, hepatitis 1  Yes 2  No
- i. Chagas' Disease or Babesiosis 1  Yes 2  No
- j. Creutzfeld-Jacob Disease 1  Yes 2  No
- k. Malaria (In the last three years) 1  Yes 2  No
- l. Possible exposure to malaria (within the last 12 months) 1  Yes 2  No

*Maternal Exposure/Social and Exposure History*

- m. Identity of the father unknown/uncertain 1  Yes 2  No
- n. Consanguinity 1  Yes 2  No
- o. Baby not genetically related to mother 1  Yes 2  No
- p. Dura mater transplant 1  Yes 2  No
- q. Growth hormone (of pituitary origin, not recombinant) or received Tegison 1  Yes 2  No
- r. Parenteral drug use<sup>1</sup> 1  Yes 2  No
- s. Prostitution<sup>1</sup> 1  Yes 2  No
- t. Use of clotting factor concentrate<sup>1</sup> 1  Yes 2  No
- u. AIDS or HIV Positivity<sup>2</sup> 1  Yes 2  No
- v. Organ or tissue transplant 1  Yes 2  No
- w. Born in, resided in, or traveled to HIV subtype O regions 1  Yes 2  No

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*Maternal Exposure/Social History IN THE LAST 12 MONTHS*

- x. Received allogeneic blood transfusion 1  Yes 2  No
- y. Tattoo, skin piercing, acupuncture<sup>3</sup> 1  Yes 2  No
- z. Accidental needle stick<sup>3</sup> 1  Yes 2  No
- aa. Contact with someone else's blood 1  Yes 2  No
- bb. Close contact with hepatitis patient or close contact with jaundiced person or received HBIG 1  Yes 2  No
- cc. Had or has treatment for STD 1  Yes 2  No
- dd. Received live virus vaccine 1  Yes 2  No
- ee. Had sex with a man who had sex, even once within the last 5 years, with another man 1  Yes 2  No
- ff. Incarcerated for >72 hours 1  Yes 2  No
- gg. Taken non-approved medications or pills in last 4 weeks 1  Yes 2  No

**4. Review of Delivery**

- a. Mother < 18 years 1  Yes 2  No
- b. Unsatisfactory amniocentesis/CVS/FISH 1  Yes 2  No
- c. Other than 3-vessel umbilical cord 1  Yes 2  No
- d. Significant placental tear, pus, inflammation 1  Yes 2  No
- e. Was pregnancy/birth and infant status inappropriate for release?<sup>4</sup> 1  Yes 2  No

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5. Review of Test Results

- a. Progenitor assay: CFU-GM = zero 1  Yes 2  No
- b. Infectious disease testing results not reviewed 1  Yes 2  No
- c. Positive microbiological culture, *specify*: \_\_\_\_\_ 1  Yes 2  No
- d. HLA samples missing or incomplete 1  Yes 2  No
- e. Positive screen for hemoglobinopathy<sup>5</sup> 1  Yes 2  No

Positive for the Following Infectious Disease Markers:

- f. Cytomegalovirus (CMV) IgM antibody 1  Yes 2  No
- g. Anti-HBc (antibody to hepatitis B core antigen) 1  Yes 2  No
- h. Syphilis 1  Yes 2  No
- i. Anti-HCV (antibody to hepatitis C virus) 1  Yes 2  No
- j. HbsAg (hepatitis B surface antigen) 1  Yes 2  No
- k. HIV-1/2 1  Yes 2  No
- l. HIV p-24 antigen 1  Yes 2  No
- m. HTLV-I/II 1  Yes 2  No

6. Positive Hepatitis B NAT Test

- a. CBU Plasma 1  Yes 2  No
- b. Maternal Serum 1  Yes 2  No

FOOTNOTES:

- <sup>1</sup> Within the last year, had sex with a person who would answer this descriptor
- <sup>2</sup> Had sex with someone with AIDS or HIV positivity in last 12 months
- <sup>3</sup> Refers only to situations in which needles were possibly used on more than one person or needles(s) were not known to be sterile.
- <sup>4</sup> Refer to Donor and Delivery Form.
- <sup>5</sup> Refer to SOP 4.4, Releasing CBU from Quarantine to Long Term Storage.

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**IF ALL ABOVE ANSWERS ARE NO, THEN THE UNIT MAY BE RELEASED FROM QUARANTINE TO LONG TERM STORAGE.**

Original Reviewer Study ID  Signature: \_\_\_\_\_

Freezer location released CBU

Freezer location Test Aliquots

Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature of Final Reviewer                      \_\_\_\_\_                      Date                        
Study ID