

MEDICAL HISTORY FORM ADMINISTRATION INSTRUCTIONS

CONFIRM THE STUDY BAR CODE ON PAGES 1 THROUGH 6 OF THIS FORM

DO NOT PLACE A STUDY BAR CODE LABEL ON THIS INSTRUCTION PAGE.

Interview Instructions

- The interview should be conducted with the maximum amount of privacy that is possible. Questions regarding sexual history must be conducted in auditory privacy.
- The COBLT interviewer may read the questions to the mother/donor, or the mother/donor may complete the questions herself. However, information in the shaded approval boxes **must** be completed by the COBLT interviewer. All answers must be recorded in ink.
- For question 12a. to 12c., the African countries are restricted to:

Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, and Nigeria
- For question 14c., close contact is defined as having either sexual contact, routine sharing of the same household, kitchen, and/or toilet facilities within the last year with a person who has had yellow jaundice at any time after age 11, or membership in a group where multiple cases of hepatitis have occurred.
- Corrections to any data item must be made at the time of the interview by drawing a single line through the incorrect information, recording the correct information, and dating and initializing the change.
- The interview **may** be stopped if an exclusion criterion is met, but it is not required to stop the interview. If the mother/donor decides not to continue, stop the interview. Document any reasons for early termination of the interview on the comments line on page 6. Exclusion criteria are listed in Section 8.2.2 of the COBLT SOP.
- When the interview is complete, review all questions before signing and dating the form.
- Return signed forms to the Coordinator at your cord blood bank.

For Interviews Conducted Eight Weeks Prior to Delivery

- Re-ask all questions marked with an asterisk following consent reaffirmation. Place initials next to each question as it is answered.

MEDICAL HISTORY FORM

Bar Code Label

Part I: Background Information

- 1. a. Date informed consent signed.....
b. If consent obtained prior to delivery, record date consent reaffirmed

- 2. Ethnic Background:
Mother Father - Caucasian/White
11 European or Western Russian
12 Middle East or North Coast of Africa
10 White (not otherwise specified)

- Mother Father - Black
21 African American
22 African Black (both parents born in Africa)
23 Caribbean Black
24 South or Central American Black
20 Black (not otherwise specified)

- Mother Father - Hispanic
41 Caribbean Hispanic
42 Mexican or Southwestern USA Hispanic
43 South or Central American Hispanic
40 Hispanic (not otherwise specified)

- Mother Father - Asian/Pacific Islander
31 Asian Indian
32 Filipino
33 Hawaiian (Polynesian)
34 Japanese
35 Korean
36 Northern Chinese
37 Southeast Asian/Southern Chinese
30 Oriental/Asian/Pacific Islander (not otherwise specified)

- Mother Father - Native American
51 Native Alaskan/Eskimo/Aleut: Tribe
52 Native American: Tribe
50 Native American (not otherwise specified)

- Mother Father - Other
90 Other specify:
88 Unknown

3. What is the father's approximate age?..... years

4. Have you ever had a serious illness?..... 1 Yes 2 No

Specify the illness :
Approved for donation: 1 Yes 2 No Study ID:

5. Did any children in your family or your baby's father's family (including uncles and aunts) die before age 10 ?..... 1 Yes 2 No

Relationship of family member to baby : Cause of death :
Approved for donation: 1 Yes 2 No Study ID:

6. Except by marriage are you and the baby's father related (i.e., cousins)?..... 1 Yes 2 No

7. Are you the baby's genetic mother?..... 1 Yes 2 No

MEDICAL HISTORY FORM

Bar Code Label

Have you had, or are you aware of your baby's father or your baby's siblings having had, any of the following:

8a. Required chronic blood transfusions?..... 1 Yes 2 No

| | |
|---|---|
| Relationship of family member etc. _____ _____ | Reason(s) _____ _____ |
| Approved for donation? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No | Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

8b. Been diagnosed with any inheritable deficiencies of the immune system, or inheritable predisposition to infections?..... 1 Yes 2 No

| | |
|---|---|
| Relationship of family member to baby _____ _____ | Type of Disease _____ _____ |
| Approved for donation? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No | Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

8c. Been diagnosed with cancer or leukemia?..... 1 Yes 2 No

| | |
|---|---|
| Relationship of family member to baby _____ _____ | Type of Cancer _____ _____ |
| Approved for donation? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No | Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

Have you had, or are you aware of your baby's father or any family member (brothers, sisters, grandparents) having had, any of the following diseases or family traits?

9a. Been told they have hemolytic anemia?..... 1 Yes 2 No

9b. Had their spleen removed to treat a blood disorder?..... 1 Yes 2 No

9c. Had their gallbladder removed for a non-traumatic reason before age 30?..... 1 Yes 2 No

| |
|---|
| Specify the reason(s): _____ |
| Approved for donation? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No |
| Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

MEDICAL HISTORY FORM

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Have you had, or are you aware of your baby's father or any family member (brothers, sisters, grandparents) having had, any of the following hereditary diseases or family traits?

- 10a. Red Blood Cell Diseases 1 Yes, not approved
 (i.e., *Thalassemia, Fanconi's Anemia, G6PD or other Red Cell Enzyme Deficiency Spherocytosis, Elliptocytosis, Porphyria, Diamond-Blackfan Syndrome*) 3 Yes, approved

| | |
|--|------------------|
| Relationship of family member to baby: | Type of Disease: |
| _____ | _____ |
| _____ | _____ |

- 2 No, not present

- 10b. White Blood Cell/ Immune Deficiencies 1 Yes, not approved
 (i.e., *SCID, Chronic Granulomatous Disease, Agammaglobulinemia, Wiskott-Aldrich, Nezelhof's Syndrome, ADA or PNP Deficiency, DiGeorge Syndrome, IgA Deficiency, Chediak-Higashi Syndrome, X-linked Lymphoproliferative Syndrome, Neutropenia or Kostmann Syndrome, Neutrophil Receptor Deficiency, Ataxia-Telangiectasia*) 3 Yes, approved

| | |
|--|---------------------|
| Relationship of family member to baby: | Type of Deficiency: |
| _____ | _____ |
| _____ | _____ |

- 2 No, not present

- 10c. Platelet Diseases 1 Yes, not approved
 (i.e., *Glanzmann's disease, Hereditary Thrombocytopenia, Hereditary Telangiectasia, Alport's Disease, Platelet Storage Pool Disease, Bernard Soulier Syndrome*) 3 Yes, approved

| | |
|--|------------------|
| Relationship of family member to baby: | Type of Disease: |
| _____ | _____ |
| _____ | _____ |

- 2 No, not present

- 10d. Metabolic/Storage Disease 1 Yes, not approved
 (i.e., *Tay-Sachs, Osteopetrosis, Mannosidosis, Fucosidosis, Newman Pick, Lesch-Nyham, Gaucher's, Hurler's, Hunter's, Leukodystrophies or San Filippo's Disease*) 3 Yes, approved

| | |
|--|------------------|
| Relationship of family member to baby: | Type of Disease: |
| _____ | _____ |
| _____ | _____ |

- 2 No, not present

- 10e. Other Diseases which run in the family 1 Yes

| | |
|---|---|
| Relationship of family member to baby: | Type of Disease: |
| _____ | _____ |
| _____ | _____ |
| Approved for donation: 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No | Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

- 2 No, not present

MEDICAL HISTORY FORM

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Part II: Blood Donor Information

Have you ever:

11a. Been refused as a blood donor or told not to donate blood? 1 Yes 2 No

Specify the reason(s): _____
Approved for donation: 1 Yes 2 No Study ID: [][][][]

11b. Had cancer, a blood disease or bleeding problem?..... 1 Yes 2 No

*11c. Had yellow jaundice (excluding neonatal jaundice and jaundice secondary to mononucleosis), liver disease, hepatitis (after age 11), or a positive test for hepatitis?..... 1 Yes 2 No

11d. Had Chagas' disease or babesiosis?..... 1 Yes 2 No

11e. Been told you or any of your blood relatives, ever had Creutzfeld-Jacob disease?..... 1 Yes 2 No

11f. Been told your family is at increased risk of Creutzfeld-Jacob disease?..... 1 Yes 2 No

11g. Had a dura mater transplant?..... 1 Yes 2 No

11h. Been given pituitary-derived Growth Hormone or taken Tegison for psoriasis?..... 1 Yes 2 No

*11i. Used a needle, even once, to take a drug not prescribed by a physician (including steroids) or (in the last 12 months) had sex with someone who has?..... 1 Yes 2 No

*11j. At any time within the last 5 years taken money or drugs for sex or (in the last 12 months) had sex with someone who has?..... 1 Yes 2 No

*11k. Taken clotting factor concentrations for a bleeding problem such as hemophilia or (in the last 12 months) had sex with someone who has?..... 1 Yes 2 No

*11l. Had AIDS or a positive test for AIDS or (in the last 12 months) had sex even once with a person who has?..... 1 Yes 2 No

11m. Had an organ transplant?..... 1 Yes 2 No

11n. Had a tissue transplant from someone other than yourself?..... 1 Yes 2 No

Specify the tissue type: _____
Approved for donation: 1 Yes 2 No Study ID: [][][][]

For the African countries listed in the Medical History Form administration instructions:

12a. Have you lived in any of those countries in the last 3 years? 1 Yes 2 No

12b. Have you lived in or traveled to any of those countries since 1977, and while there did you receive a blood transfusion or any medical treatment with a product made from blood?..... 1 Yes 2 No

*12c. Have you had sexual contact with anyone who was born in or lived in any of those countries since 1977?..... 1 Yes 2 No

MEDICAL HISTORY FORM

Bar Code Label

In the last three years have you:

*13a. Been outside the USA or Canada? 1 Yes 2 No

Where and when: _____
Approved for donation? 1 Yes 2 No Study ID: [][][][]

13b. Had malaria?..... 1 Yes 2 No

In the last 12 months have you:

*14a. Received blood from someone other than yourself? 1 Yes 2 No

*14b. Had a tattoo, ear or skin piercing, acupuncture, accidental needle stick, or come in contact with someone else's blood?..... 1 Yes 2 No

Specify the reason(s): _____
Approved for donation? 1 Yes 2 No Study ID: [][][][]

*14c. Had close contact with a person with yellow jaundice or hepatitis, or have you been given Hepatitis B Immune Globulin (HBIG)? 1 Yes 2 No

*14d. Had or been treated for syphilis or gonorrhea or had a positive test for syphilis?..... 1 Yes 2 No

*14e. Had any shots or vaccinations?..... 1 Yes 2 No

Specify: _____
Approved for donation? 1 Yes 2 No Study ID: [][][][]

*14f. Had sex with a man who had sex even once within the last 5 years with another man?..... 1 Yes 2 No

14g. Been incarcerated in jail or prison for more than 72 consecutive hours?..... 1 Yes 2 No

Additional Questions :

*15a. Taken any pills or medications other than prenatal vitamins or iron supplements in the last four weeks?..... 1 Yes 2 No

Type of pills taken: _____
Approved for donation? 1 Yes 2 No Study ID: [][][][]

*15b. Do you, or anyone living or working in your household, have tuberculosis? 1 Yes 2 No

15c. Do you understand that if you have the AIDS virus you can give it to someone else even though you feel well and have a negative AIDS test?..... 1 Yes 2 No

END OF DONOR INTERVIEW

Complete Part III Interview Information separately.

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Part III: Interview Information

16. Was consent withdrawn at any time during the interview?..... 1 Yes 2 No

17. Who was present for the interview during genetic history questions?

1 Mother only 2 Father and Mother 3 Other, specify: _____

18. Was mother questioned in auditory privacy for sexual history?..... 1 Yes 2 No

Comments: _____

Interviewer's Signature

Date

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

Study ID

OPTIONAL
INFORMED CONSENT REAFFIRMATION CHECKLIST

(For CBB use only. This data is not part of the COBLT Internet Data System.)

Have all questions with an asterisk been reaffirmed?..... 1 Yes 2 No, consent < 8 weeks

Has the reaffirmation consent date been recorded for Question 1b?..... 1 Yes 2 N/A

Signature of Person Reaffirming Consent: _____