

CHAPTER 8
DATA COLLECTION

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8.1 OVERVIEW

The initial subsection of this chapter describes some of the steps taken to maximize donor confidentiality as well as maintain a linkage between donor and the unit. Note that no information on the identity of the donor is submitted to the MCC. The linkage is maintained entirely at the cord blood banking centers, which are responsible for physical security of the process.

Subsequent sections include all of the data forms used to capture information related to maternal history, eligibility, delivery, and cord blood unit collection. In addition, all forms for centrally stored data describing the receipt, processing, infection screening, characterization of the unit and release of the unit from quarantine and from permanent storage into the storage bank are provided. Forms submission requirements are summarized in Table 8.1.

For each CBU, the collection, processing, testing and storage activities will be completed during a quarantine period. CBUs will be released from quarantine storage to long term storage following submission of a CBU Exclusion and Quarantine Release Form indicating the long term storage freezer locations of the CBU and associated samples. After the CBU is released to long term storage and becomes available as a potential stem cell source, data related to that CBU cannot be modified or deleted, i.e. all data records pertaining to that CBU will be locked. The locking sequence is as follows:

Category 1

All records including the CBU Disposition Form will be locked when the following condition is met:

1.A Immediately after a CBU is shipped for transplant.

Category 2

All records excluding the CBU Disposition Form will be locked when the following condition is met:

2.A Immediately after the CBU is placed in the COBLT Search Registry.

For locked data records, only three types of data can be subsequently updated: 1) additional HLA testing may further characterize the unit, 2) a CBU disposition form may be filed to indicate use of or discarding of the CBU, and 3) freezer locations of samples and CBUs may be modified.

Requests to unlock a bar code may be made to the Data Manager at the MCC. Requests must be made by the CBB Principal Investigator (PI), or his/her designate, and must contain the full ISBT ID bar code to be unlocked, the reason of the request, and the requestor's COBLT certification number. In addition, the request should include the current status of the CBU (e.g., shipped for transplant, eligible for search, currently reserved by a transplant center). Requests may be faxed or e-mailed to the MCC data management e-mail address (cobltdm@emmes.com).

The CBB PI and CBB Coordinator will be notified immediately by the MCC when the bar code is unlocked. Records will remain unlocked for 4 days. During this time, data may be added, modified, or deleted.

Note that the sources for these data are varied; some describe clinical characteristics of the mother and delivery, some derive from the processing and distribution tasks, and some come from the special laboratory testing. Because of the data volume, the HLA reference labs will submit electronic records of their testing results. The remainder of the data will be incorporated into the MCC developed data system at the banks following the data specifications which follow in the form subsections.

TABLE 8.1
FORMS SUBMISSION REQUIREMENTS

Mother consented but no collection obtained

If a label has not been assigned

No forms are expected

If a label has been assigned

CBU Disposition Form indicating that the label set was discarded

Collected CBU but processing not initiated

Medical History Form
CBU Collection and Receipt Form
CBU Disposition Form

Collected CBU and processing initiated but not completed

Medical History Form
CBU Collection and Receipt Form
CBU Processing Form
CBU Disposition Form

Collected, processed, cryopreserved, and quarantined CBU, AND either an exclusion criteria is met or CBU is transferred to long term storage

Medical History Form
CBU Collection and Receipt Form
CBU Processing Form
CBU Cryopreservation Form
Donor and Delivery Information Form
Maternal Sample Form
Graft Characterization Form
CBU Exclusion and Quarantine Release
CBU Disposition Form (due at removal from quarantine or long term storage)

CBU label set released but not assigned, and discarded

CBU Disposition Form indicating that the label set was discarded

8.2 DATA COLLECTION FORMS

8.2.1 Volunteer Cord Blood Donor Identification Form

8.2.2 Medical History Form

MEDICAL HISTORY FORM
EXCLUSION CRITERIA FOR COLLECTED CORD BLOOD UNITS

Part I: Background Information

- | | |
|--|---|
| 1. Date Informed Consent Signed | Exclude unit if mother/donor has not signed or reaffirmed an informed consent. |
| 2. Ethnic Background | See question 3. |
| 3. Father's Age | If question 2, Ethnic Background, is coded 88-Unknown for the father, and the father's approximate age is unknown, then exclude the unit. |
| 4. Serious Illness | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |
| 5. Childhood Deaths | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |
| 6. Related Marriages | Exclude unit if mother answers 1-Yes. |
| 7. Genetic Mother | Exclude unit if mother answers 2-No. |
| 8a. Chronic Blood Transfusion | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |
| 8b. Inheritable Deficiencies | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |
| 8c. Cancer/Leukemia | If mother answers 1-Yes then:
If the cancer is documented as basal or squamous cell skin cancers do not exclude the unit.

Exclude the unit if any other type of cancer or leukemia in a first degree relative of the infant (mother, father, siblings) is reported. |
| 9a. Hemolytic Anemia | Exclude unit if mother answers 1-Yes. |
| 9b. Spleen Removed to Treat a Blood Disorder | Exclude unit if mother answers 1-Yes. |
| 9c. Gallbladder Removed for a Non-Traumatic Reason | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |

- | | |
|----------------------------------|---|
| 10a. Red Blood Cell Disease | Exclude unit if mother answers 1-Yes. |
| 10b. White Blood Cell Deficiency | Exclude unit if mother answers 1-Yes. |
| 10c. Platelet Disease | Exclude unit if mother answers 1-Yes. |
| 10d. Metabolic/Storage Disease | Exclude unit if mother answers 1-Yes. |
| 10e. Other Diseases | If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB. |

Part II: Blood Donor Information

Questions With No Time Restrictions

- | | |
|-------------------------------------|---|
| 11a. Refused as Blood Donor | If mother answers 1-Yes then:
If refusal was for anemia, or because of mechanical problems with donating blood (e.g., unsuccessful donation, hematoma, etc.), then the unit is acceptable. If refusal was due to a history of risk behavior for transfusion-transmittable disease, then refer the form to the Medical Director if no other exclusion criteria is recorded.

For answers other than the above, refer the history form to the Medical Director at the CBB. |
| 11b. Cancer, Blood Diseases, etc. | Exclude unit if mother answers 1-Yes, unless the cancer is documented as basal or squamous cell skin cancers. |
| *11c. Yellow Jaundice, etc. | Exclude unit if mother answers 1-Yes. |
| 11d. Chagas Disease or Babesiosis | Exclude unit if mother answers 1-Yes. |
| 11e. Creutzfeld-Jacob Disease (CJD) | Exclude unit if mother answers 1-Yes. |
| 11f. Risk CJD | Exclude unit if mother answers 1-Yes. |
| 11g. Had Dura Mater Transplant | Exclude unit if mother answers 1-Yes. |
| 11h. Growth Hormone or Tegison | Exclude unit if mother answers 1-Yes. |
| *11i. Needle Use | Exclude unit if mother answers 1-Yes. |
| *11j. Money for Drugs/Sex | Exclude unit if mother answers 1-Yes. |

- *11k. Clotting Factor Exclude unit if mother answers 1-Yes.
- *11l. AIDS/Sex Exclude unit if mother answers 1-Yes.
- 11m. Organ Transplant Exclude unit if mother answers 1-Yes.
- 11n. Allogeneic Tissue Transplant If mother answers 1-Yes then:
Refer the history form to the Medical Director at the CBB.

Questions Restricted to 1977 and the African Countries of Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria

- 12a. Lived in One of Listed Countries in the Last 3 Years Exclude unit if mother answers 1-Yes.
- 12b. Travel to One of Listed Countries Exclude unit if mother answers 1-Yes to traveling to one of the listed countries since 1977 AND receiving a blood product while there.
- *12c. Sexual Contact with Resident Exclude unit if mother answers 1-Yes.

Questions Restricted to the Last 3 Years

- *13a. Traveled Outside USA/Canada If mother answers 1-Yes then:
Exclude units collected from mothers who have resided in an area endemic for malaria within the past 3 years. Endemic areas are listed in Health Information for International Travelers published by the Centers for Disease Control (CDC). The most current publication must be used when determining whether a mother has traveled to an endemic area. Updated information on regions may be obtained 24 hours a day by calling the CDC Malaria Hotline at (404) 332-4555.

If the mother resides in the USA/Canada or is from an area not endemic for malaria, and has traveled outside the USA or Canada in the PAST YEAR, determine whether or not the mother has traveled to an area endemic for malaria. Units collected from mothers who have traveled to a malarial area in the PAST YEAR where travel was limited to daylight hours (e.g. flight connection or cruise ship port visits) are acceptable. Otherwise, if yes, exclude unit.

- 13b. Malaria in Last 3 years Exclude unit if mother answers 1-Yes.

Questions Restricted to the Last 12 Months

- *14a. Allogeneic Blood Transfusion Exclude unit if mother answers 1-Yes.
- *14b. Tattoo, Ear/Skin Piercing, etc. If mother answers 1-Yes then:
It is important to determine if the mother has been exposed to transfusion-transmittable disease through non-sterile needles or contact with someone else's blood.

Exclude units if the mother reports contact with blood through nonsterile needle sticks, a human bite that results in a wound which breaks the skin (including bites from children), electrolysis, or ear/body part piercing or acupuncture procedures if needles were previously used or not sterile or if the mother does not know if the needles may have been reused.

Exclude the unit if the mother reports having a tattoo in the last 12 months.

Units are not excluded if the mother reports ear or body piercing using an ear piercing gun that has sterile disposable supplies, or receiving autologous blood products/tissue.
- *14c. Contact with Yellow Jaundice, etc. Exclude unit if mother answers 1-Yes. 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.
- *14d. Treated/Tested Syphilis, Gonorrhea Exclude unit if mother answers 1-Yes.
- *14e. Shots/Vaccinations If mother answers 1-Yes then:
Exclude the unit if the mother reports having received HBIG, or a live viral vaccine, or an unlicensed vaccine, or rabies vaccine following a bite by a rabid animal or one suspected to be rabid.
- *14f. Sex With Man Who Had Sex With a Man Exclude unit if mother answers 1-Yes.
- 14g. Jail 72 Hours Exclude unit if mother answers 1-Yes.

Additional Questions

- | | |
|--|---|
| *15a. Pills or Medications | If mother answers 1-Yes then:
If pills or medication were reported as prenatal vitamins or iron supplement, then unit is acceptable. Otherwise, refer the history form to the Medical Director at the CBB. |
| *15b. TB Infection/Exposure | Exclude unit if mother answers 1-Yes. |
| 15c. AIDS Question | No exclusion. |
| <i>Part III: Interview Information</i> | |
| 16. Consent Withdrawn at Any Stage | Exclude unit if mother answers 1-Yes. |
| 17. Present for Genetic History | No exclusion. |
| 18. Mother Questioned in Private | Exclude unit if mother answers 2-No. |

* Questions to be re-asked following consent reaffirmation for interviews conducted pre-delivery.

8.2.3 Donor and Delivery Information Form

**EXCLUSION CRITERIA FOR
DONOR AND DELIVERY INFORMATION FORM**

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|--|---|
| 1. Mother's Age | Exclude unit if mother's age is < 18 years. |
| 2. Evidence of Placental Infection | Exclude unit if 1-Yes. |
| 3. Membrane Rupture | <i>Data collection - no exclusion</i> |
| 4. Prenatal Antibiotics | Exclude unit if 1-Yes. |
| 5. Mother Afebrile | Exclude unit if 2-No. |
| 6. Date/Time of Delivery | <i>Data collection - no exclusion</i> |
| 7. Type of Delivery | <i>Data collection - no exclusion</i> |
| 8. Gestational Age at Birth | <i>Data collection - no exclusion</i> |
| 9a. Infant Gender | <i>Data collection - no exclusion</i> |
| 9b. Infant Weight | <i>Data collection - no exclusion</i> |
| 10. Single Birth | Exclude unit if 2-No. |
| 11. Infant Afebrile | Exclude unit if 2-No. |
| 12. Evidence of Infant Sepsis | Exclude unit if 1-Yes. |
| 13. Free of Congenital Infection, etc. | Exclude unit if 2-No. |
| 14. Free of Congenital Abnormalities | Exclude unit if 2-No. |
| 15. Pregnancy or Birth Complications | If answer 1-Yes then:
Refer the form to the Medical Director at the CBB. |

8.2.4 Maternal Sample Form

8.2.5 CBU Collection and Receipt Form

8.2.6 CBU Processing Form

8.2.7 CBU Cryopreservation Form

8.2.8 Graft Characterization Form

8.2.9 CBU Exclusion and Quarantine Release Form

8.2.10 CBU Disposition Form

8.3 LOGS

8.3.1 Label Release Log

8.3.2 Shipping Log

8.3.3 HLA Request Log

8.4 **REPORTS**

8.4.1 **CBB Monthly Recruitment Report**

8.4.2 CBU Processing QA Report

8.5 HLA TYPING DATA COLLECTION

HLA data for newly typed CBUs from the typing laboratories will be sent weekly to the MCC. This data will consist of:

- ! Specimen Identification
- ! Typing Date
- ! Assigned types at each of the HLA A,B and DRB1 loci
- ! Potentially present nucleotide sequences for the above
- ! Typing Method

Submission of electronic records will be via the Internet.

Additional confirmatory typing of specimens will be reported with notation as to the date and results. Additional loci may also be typed at the time of confirmatory typing.