

CHAPTER 2
MATERNAL/DONOR ISSUES

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2.1 EDUCATION

Principle

Education will be provided to a potential mother/donor of an umbilical cord blood unit so that she can make an informed choice on donation of her infant's cord blood to the Cord Blood Transplantation Study. At the very least, information will be given at the time informed consent is requested. However, attempts will be made to provide education to potential donors and to the community at large, using the guidelines listed below.

Guidelines

1. Brochures (Appendix A) may be placed in OB/delivering physician's offices. The brochure describes the donation and the COBLT study in generally understandable terms and includes a phone number to call for further information.
2. Brochures can be translated into several different languages, including, but not limited to English, Spanish, Chinese, Japanese, Vietnamese and Korean.
3. In-service sessions may be provided for the OB's/delivering physicians/nurse midwives to educate them about the purpose of the project and to give them the information they need to answer their patients' questions when they arise.
4. Public service announcements describing the Cord Blood Transplantation Study may be aired on local television and radio stations. Both local and nationally recognized celebrity spokespersons from various ethnic groups may be recruited to make these announcements.
5. Presentations before community groups can provide further education to potential donors. These presentations may include an appearance by celebrity spokespersons from various ethnic groups, with an instructional presentation and question-answer session given by the medical and technical staff of the Cord Blood Banks.
6. Booths may be set up at community events to promote the Cord Blood Transplantation Study and to provide information to the public regarding the program. Appearances by celebrity spokespersons may be arranged, with the booths manned by the medical and technical staff of the Cord Blood Banks and trained volunteers.
7. A phone line may be set up to facilitate responding to a potential donor's questions. If established, the phone line could have a recorded message, available in several languages, which could provide the caller with basic information and allow them to leave their name and phone number so that their call may be returned.

2.2 OBTAINING INFORMED CONSENT

Principle

Informed consent is a process that begins with information, encompasses a dialogue, and culminates with a written, signed document. The informed consent process must begin prior to the start of active labor and be obtained from every mother/donor, as detailed below. Consent will not be obtained during active labor or while the mother is under the influence of sedation or mood altering medications. Active labor should be determined at each collection center after consultation with the mother/donor's medical providers. Mothers/donors who do not receive information about the study prior to the start of active labor will not be considered eligible to participate in the study.

Obtaining Informed Consent

1. The informed consent process may start after the 22nd week of pregnancy and must be initiated prior to the start of active labor.
2. If written consent is obtained prior to delivery, verbal affirmation will be obtained in the hospital prior to administration of the maternal history questionnaire and drawing of maternal blood.
3. If written informed consent is not obtained prior to the start of active labor, verbal consent or a completed preliminary informed consent document, as well as documentation that the informed consent process started prior to the start of active labor, must be obtained prior to CBU and maternal sample collection. Consent must be reaffirmed using the full informed consent document following CBU collection and before hospital discharge.
4. Three signed copies of the informed consent document will be obtained. One copy will be placed in the mother/donor medical chart and one copy in the confidential CBB file. The third copy will be given to the mother/donor. No study bar code labels should be placed on the informed consent document in the mother/donor medical chart or given to the mother/donor. A study bar code label may be placed on the consent document for the confidential CBB file.
5. The Collection/Distribution Coordinator will alert the laboratory at the earliest possible time to discard the unit if consent is not given for donation of the cord blood unit, or if the medical history indicates that the unit should not be kept.

2.3 OBTAINING DONOR MEDICAL HISTORY AND DELIVERY INFORMATION

Principle

Obtaining a detailed medical history from mothers/donors provides a method of screening cord blood units for hereditary and infectious diseases which could potentially be transmitted to a CBU recipient. The Medical History Form is a questionnaire designed to review the past and current medical history of the mother/donor. The questionnaire is completed by trained personnel during an interview with the mother/donor following delivery and informed consent.

Obtaining information about the delivery of the donor's infant provides a method of screening cord blood units. The Donor and Delivery Information Form should be completed from a review of the medical chart after an informed consent has been signed.

Materials

Volunteer Cord Blood Donor Information Form
Informed consent document
Medical History Form
Donor and Delivery Information Form
Confidential manila envelope
Ink Pen
Bar code reader (*optional*)

Procedure

Obtaining Medical History

1. Obtain or reaffirm informed consent to participate in the study and complete the Volunteer Cord Blood Donor Information Form. Place one copy of the informed consent for the CBB confidential file in the confidential manila envelope.
2. Take the Medical History Form from the collection kit paperwork and verify that the bar code number on each page matches the bar code number on the Volunteer Cord Blood Donor Information Form. Place the Volunteer Cord Blood Donor Information Form in the confidential manila envelope.
3. Read each question on the Medical History Form to the mother/donor and record the answers using an ink pen. The interview should be conducted with the maximum amount of privacy that is possible. Document items as indicated on the form. Corrections to the form must be made at the time of the interview. Corrections must be made by drawing a single line through the incorrect information, recording the correct information, and dating and initializing the change.
4. The interview may be stopped if an exclusion criterion is met or if the mother/donor decides not to continue. If the interview is not completed, document the reason(s) for not completing the

interview on the 'Comment' line at the end of the form. As soon as possible, the processing laboratory should be notified to inform them that the unit is now unavailable so that unnecessary testing and processing can be avoided.

5. When all questions have been asked, review each page and make corrections or additions as necessary before finishing the interview.
6. Sign and date the form. Place the completed Medical History Form with the confidential manila envelope.

Obtaining Delivery Information

1. Remove the Volunteer Cord Blood Donor Information Form from the confidential manila envelope and verify that the hospital ID and mother/donor name matches the medical record. Verify that the bar code number of the Donor and Delivery Information Form matches the bar code number on the Volunteer Cord Blood Donor Information Form.
2. Return the Volunteer Cord Blood Donor Information Form to the confidential manila envelope. If the maternal blood samples have already been obtained, then seal the confidential manila envelope and sign in ink across the seal.
3. Complete the Donor and Delivery Information Form using the medical chart.
4. Sign and date the form. Place the form with the confidential manila envelope for return to the Cord Blood Bank.

Quality Control

1. The bar code numbers will be checked before each interview.
2. The questionnaire will be conducted by trained personnel.
3. The questionnaire will be reviewed, at minimum, by the person administering the questionnaire at the time of the interview for completeness and accuracy.
4. Linkage of the unit to the mother/donor will be maintained using the Volunteer Cord Blood Donor Information Form. Confidentiality will be maintained by placing confidential forms (VCBDI and one copy of the informed consent) in the confidential manila envelope, sealing the envelope, and placing a signature across the seal.
5. Cord Blood Banks will have procedures in place to allow the mother/donor to notify confidentially the interviewers of changes to the Medical History Form.

2.4 OBTAINING MATERNAL BLOOD SAMPLES

Principle

Samples for infectious disease testing will be obtained from the mother/donor of the umbilical cord blood unit. These samples will be collected and handled according to the following procedure so that samples are obtained as efficiently and with as little risk of error in identification as possible.

Policy

This sample collection procedure will be performed either by employees of the collection site or employees of the Cord Blood Bank, as determined by the policies of the individual collection sites. Samples will be obtained at the time consent is given or reaffirmed and after medical history is taken following delivery.

Materials

Two 7 ml red-top (serum-clot) Vacutainer tubes
One 7 ml lavender-top (EDTA) Vacutainer tube
Mother's hospital labels
Volunteer Cord Blood Donor Identification Form
Maternal Sample Form
Biohazard specimen bag
Manila envelope containing mother's sample bar code labels

Procedure

When consent is completed, the Clinical Research Nurse (CRN) either draws the blood samples or requests the collection site's phlebotomist to draw the mother's samples, based on the policies of the individual collection sites. The appropriate procedure given below will be followed, based on the identity of collecting personnel.

For Samples Drawn by Cord Blood Bank CRN

1. The CRN verifies the bar code label from the manila envelope matches that on the Volunteer Cord Blood Donor Identification Form and then labels two 7ml red top and one 7ml lavender top Vacutainer tubes with the bar code labels.
2. The CRN verifies the mother's hospital label on the Volunteer Cord Blood Donor Identification Form matches the mother's wrist band.
3. The CRN draws the blood samples from the mother's arm into the supplied tubes.
4. The CRN places the samples and the extra mother's sample bar code labels in a biohazard specimen bag for transport to the Cord Blood Bank.

5. The CRN verifies that the bar code label on the Volunteer Cord Blood Donor Identification Form matches the bar code labels on the Maternal Sample Form and collection tubes. The CRN records on the Maternal Sample Form the date and time when the samples were drawn, then signs the form, and adds the study ID number.
6. The completed Maternal Sample Form is placed with the confidential manila envelope for return to the Cord Blood Bank.

For Samples Drawn by the Collection Site's Phlebotomist

1. After consent is obtained, the Clinical Research Nurse (CRN) requests the collection site's phlebotomist to draw the mother's samples. The CRN labels two 7ml red top and one 7ml lavender top Vacutainer tubes with the mother's hospital labels. The phlebotomist draws the blood samples from the mother's arm into the supplied tubes.
2. Immediately after the samples are drawn, they are given to the CRN who verifies the labels on the tubes match the hospital label on the Volunteer Cord Blood Donor Identification Form.
3. After the consent and medical history interview are completed, the CRN verifies the bar code label from the manila envelope matches the bar code label on the Volunteer Cord Blood Donor Identification Form, removes the hospital labels from the sample tubes and relabels the tubes with the bar code labels.
4. The CRN places the samples and the extra mother's sample bar code labels in a biohazard specimen bag for transport to the cord blood bank.
5. The CRN verifies that the bar code label on the Volunteer Cord Blood Donor Identification Form matches the bar code labels on the Maternal Sample Form and collection tubes. The CRN records on the Maternal Sample Form the date and time when the samples were drawn, then signs the form, and adds the study ID number.
6. The completed Maternal Sample Form is placed with the confidential manila envelope for return to the Cord Blood Bank.

Quality Control

For Samples Drawn by Cord Blood Bank CRN

1. The CRN verifies the hospital label on the Volunteer Cord Blood Donor Identification Form matches the mother's wrist band and signs the form.
2. The CRN cross checks the bar code labels from the manila envelope with the Volunteer Cord Blood Donor Identification Form before labeling the tubes into which the samples are drawn.
3. Only one set of forms, labels, and tubes are to be brought into the room at one time. If other interviews are to be conducted immediately before or after, the forms, labels, and tubes for

other donors are to be left in a secure location outside the room.

For Samples Drawn by the Collection Site's Phlebotomist

1. The CRN and the phlebotomist verify the patient's arm band with the hospital labels on the tubes and sign the Volunteer Cord Blood Donor Identification Form.
2. The CRN verifies the hospital labels on the tubes with the Volunteer Cord Blood Donor Identification Form, and cross checks the bar code labels from the manila envelope with the Volunteer Cord Blood Donor Identification Form before relabeling the tubes into which the samples have been drawn.
3. Only one set of forms, labels, and tubes are to be brought into the room at one time. If other interviews are to be conducted immediately before or after, the forms, labels, and tubes for other donors are to be left in a secure location outside the room.

2.4.1 **Samples for HLA Typing**

Principle

Blood samples obtained from the mother/donor following consent will be processed and stored for HLA typing at the time a match for a potential recipient is identified for the corresponding CBU.

Specimen

One 7 ml lavender (EDTA) top Vacutainer tube containing the mother's blood sample. Samples for HLA typing will be delivered to the Cord Blood Bank processing laboratory within 24 hours of collection of the sample. Upon arrival in the laboratory, the date and time of receipt will be recorded on the Maternal Sample Form and the samples will be stored at 4°C prior to processing.

Equipment

Bar code scanner
Computer

Materials

Three cryovials
Transfer pipette
Mother's bar code labels
Nunc Plastics

Procedure

1. Three ml of blood are removed from the Vacutainer tube with a transfer pipette, and divided equally between the three cryovials, labeled with the mother's sample bar code label.

2. Store the tubes in designated quarantine space in a mechanical freezer at $\leq -20^{\circ}\text{C}$ until requested for HLA typing. Record the fact that processing for HLA typing is complete, as well as the location of quarantine storage, on the Maternal Sample Form and maternal sample database.
3. The Vacutainer tube with the remaining blood sample is set aside to be processed according to SOP 2.4.3 for infectious disease amplification and testing.

Quality Control

1. Only one set of mother's samples will be processed at a time.
2. Bar code numbers on the labels and the tubes will be verified against the original tube at each addition of a new label to a tube.

2.4.2 Samples for Infectious Disease Testing

Principle

Blood samples obtained from the mother/donor following consent will be processed prior to testing for infectious diseases. A serum sample will be stored pending results of the infectious disease testing for confirmatory testing if required. Each of the participating cord blood banks must determine the sample requirements for the laboratories performing their infectious disease testing. If the testing laboratory uses manual methods, the serum samples may be stored at or below -20°C prior to shipment. If the testing laboratory uses automated methods, they may require that the serum samples be stored at 4°C prior to shipment within 24-48 hours.

Specimen

Two 7 ml red top Vacutainer tubes, labeled with the mother's sample bar code labels and containing the mother's blood samples will be delivered to the Cord Blood Bank processing laboratory within 24 hours of collection of the sample. Upon arrival in the laboratory, the date and time of receipt will be recorded on the Maternal Sample Form and the samples will be stored at 4°C prior to processing. Samples must be processed and frozen within 5 days of collection.

Materials

Seven cryovials

Mother/donor bar code labels

Transfer pipette

Small manila envelope containing a set of bar code labels with unique number followed by mother's sample identifier (the letter M)

Procedure

1. Centrifuge the red-top Vacutainer at 1500g for 15 minutes.

2. Using the transfer pipette, divide the serum equally among the cryovials.
3. If samples are to be shipped frozen to the testing laboratory, all tubes may be stored at $\leq -20^{\circ}\text{C}$ prior to shipment. If the testing facility requires that the samples not be frozen, store six of the tubes at 4°C prior to shipment. Store the seventh tube in designated quarantine space in a mechanical freezer at $\leq -20^{\circ}\text{C}$ for future testing if needed.
4. Record the fact that processing for ID samples is complete, as well as the location of quarantine storage for the seventh sample, on the Maternal Sample Form and maternal sample database.

Quality Control

1. Only one set of mother's samples will be processed at a time.
2. Bar code numbers on the labels and the tubes will be verified against the original tube at each addition of a new label to a tube.

2.4.3 Samples for Infectious Disease Amplification Study

Principle

Blood samples obtained from the mother/donor following consent will be processed prior to testing for infectious diseases. Upon arrival in the laboratory, the date and time of receipt will be recorded on the Maternal Sample Form and the samples will be stored at 4°C prior to processing. Plasma samples will be frozen and sent in batches to Gen-Probe for infectious disease amplification and testing.

Specimen

One 7ml lavender-top Vacutainer tube with approximately 4ml of blood remaining, following processing as in SOP 2.4.1.

Materials

Transfer pipette
One cryovial

Procedure

1. The Vacutainer tube is centrifuged at $1500 \times g$ for 15 minutes.
2. The plasma is removed to the cryovial, using the transfer pipette.
3. Tubes are stored at $\leq -20^{\circ}\text{C}$ prior to shipment to Gen-Probe for infectious disease amplification and testing.

Quality Control

1. Only one set of mother's samples will be processed at a time.
2. Bar code numbers on the labels and the tubes will be verified against the original tube at each addition of a new label to a tube.

2.5 DONOR CONFIDENTIALITY AND LINKAGE

Principle

Protection of the identity of the mother and infant donors of umbilical cord blood units while at the same time maintaining linkage of a particular unit to its mother/donor is of the highest priority. The following procedures and guidelines will be followed to ensure that linkage and donor confidentiality are preserved and protected:

Materials

Set of bar code labels
Mother's hospital label
Volunteer Cord Blood Donor Identification Form

Procedure

Establishment of Linkage and Confidentiality at the Time of Cord Blood Harvest and Consent Process

1. Initial linkage of the mother/donor to the CBU will be established prior to the infant's birth when the cord blood collector places both a unique bar code label and the mother's hospital label on a Volunteer Cord Blood Donor Identification Form. This form will be placed with the basin.
2. Prior to delivery, the cord blood collector places a unique bar code label on the basin in which the placenta will be placed. This basin will be placed in the delivery room with the Volunteer Cord Blood Donor Information Form.
3. Following the delivery of the placenta, a member of the delivery staff or Clinical Research Nurse (CRN) will verify that the patient's name and hospital number on the patient's wristband matches the hospital number and name on the Volunteer Cord Blood Donor Identification Form, and will verify that the bar code number on the basin matches the bar code number on the Volunteer Cord Blood Donor Information Form. The staff member or CRN will sign the Verification of Placental Donor Identification statement on the back of the Volunteer Cord Blood Donor Identification Form, and hand the basin containing the placenta and the Volunteer Cord Blood Donor Information Form to the cord blood collector.
4. The cord blood collector will verify that the bar code number on the basin matches the bar code number on the Volunteer Cord Blood Donor Identification Form and on the collection bag and labels in the kit and sign the Cord Blood Collector's Verification Statement.
5. The Volunteer Cord Blood Donor Identification Form with the attached bar code and hospital labels will be placed in the confidential manila envelope with the collection kit in a secured location until the Cord Blood Bank CRN removes it at the time medical history, maternal blood samples, and delivery information are obtained or until he/she is notified by collection or processing personnel that the unit was not suitable for collection or storage.

Maintenance of Linkage and Confidentiality Following Consent

1. It is the duty of the Director/Principal Investigator (PI) of the Cord Blood Bank, and his/her designees to protect the identity of the mother/donors. Access to information linking the mother/donor to the unique bar coded unit number for a particular umbilical cord blood unit will be limited to key personnel authorized by the Director/PI of the Cord Blood Bank.
2. Computer records containing linkage and confidential information will be maintained. Access to these records will be controlled by a multi-level security system requiring passwords and available only to key personnel authorized by the Director/PI of the Cord Blood Bank. Passwords will be changed at a minimum of every three months.
3. Computer records will be maintained as encrypted files which will be backed up nightly. A weekly backup for off-site storage will also be performed.
4. Hard copies of records and computer backup files containing linkage and confidential information will be stored in locked file cabinets in a locked room in a secure area. Access to those records will only be given to key personnel authorized by the Director/PI of the Cord Blood Bank.

Quality Control

At the Time of Cord Blood Harvest and Consent Process

1. Only one Volunteer Cord Blood Donor Identification Form and one labeled basin at a time are to be brought into the delivery room. **Only one set of forms, labels, and tubes are to be available in the mother's room while data and blood samples are being collected.** If other interviews are to be conducted immediately before or after, the forms, labels, and tubes for other donors are to be left in a secure location outside the room.
2. The donor identification sheet containing linkage between the mother/donor and the unique bar coded unit number will be accessible only to the Cord Blood Bank phlebotomist and/or the research nurse, members of the labor and delivery staff, and personnel authorized by the CBB Director/PI.
3. Signatures of verification will be obtained when the placenta is given to the cord blood collector and when the maternal blood samples are obtained by the phlebotomist. These signatures will attest to verification of the mother/donor identity by examination of the mother's wrist band and comparison of the hospital number with the hospital label on the Volunteer Cord Blood Donor Identification Form and of the study bar code number on the Volunteer Cord Blood Donor Information Form and the basin.
4. All Cord Blood Bank and Cord Blood Transplant Center employees will sign confidentiality statements protecting the identities and other medical and personal information obtained from the mother/infant donors participating in this project. The importance of patient confidentiality will be emphasized to Cord Blood Bank and Cord Blood Transplant Center employees at the

time of their orientation to the project.

Following Consent

1. Access to all confidential records including computer records and hard copies will be limited to key personnel authorized by the Director/PI of the Cord Blood Bank.
2. A computer security system with passwords and limited access only to key personnel will protect computer records, which will be stored as encrypted files to further limit accessibility. Backup files with storage off-site will be performed to further protect vital information.
3. Hard copies of records and computer backup files containing linkage and confidential information will be stored in locked file cabinets in a locked room in a secure area. Access to those records will only be given to key personnel as authorized by the Director/PI of the Cord Blood Bank.

2.6 NOTIFYING DONORS OF POSITIVE INFECTIOUS AND GENETIC DISEASE TEST RESULTS

Principle

Donor notification is a sensitive area as it relates to donor health, product safety, and prevention of possible disease transmission. This procedure serves as a guide in the donor notification process.

Materials

Record of Donor Notification

Confidential donor file

Notification letter(s) for positive infectious disease tests and genetic screening, as appropriate

General Notification Procedures

1. The donor notification process should be initiated within seven working days from receipt of confirmed positive test results.
2. Compliance with state or local regulations is required.

Methods of Notification

1. Letters are an acceptable method of donor contact for all situations described in this procedure that require notification. Some test results also require donor counseling services.
2. Use notification letters such as those in Appendix C for each specific blood test or health history finding. No further donor contact is required unless counseling is indicated, a donor has questions, or a letter was returned as undeliverable.
3. Include appropriate fact sheet(s) with each notification letter.
4. If state or local laws/regulations require reporting of individuals found to be positive for certain laboratory tests, maintain a written copy of such law(s) in your files. Include the following statement in the notification letter:

We are required by law to report the results of this test to the *insert state or local name here* Department of Health. It is possible that a health department official may communicate with you further on this matter.

5. Mail first notification letters for HIV in a plain, white envelope via certified mail. Mail will automatically be forwarded by the postal service to a current address. Send all other notification letters via first class mail.
6. If the donor does not contact the CBB in reference to the first HIV notification letter, the CBB should attempt to contact the donor by telephone as detailed below. If, after two telephone

attempts, the CBB fails to contact the donor, the second letter for HIV notification should be sent in a white envelope via certified mail.

7. All notification letters returned and marked undeliverable should be followed up in order to locate the donor's current address.
 - a. Try to contact the donor at home by telephone.
 - b. If unable to contact the donor at home, the "emergency" telephone listed on the Volunteer Cord Blood Donor Information Form should be attempted.
 - c. If unable to contact the donor at the above two numbers, and a work telephone number is available, attempt to contact the donor at work only to obtain a correct mailing address. Speak only with the donor and specify that an updated mailing address is required. Do not discuss any blood test information on the telephone.
 - d. If unable to obtain the donor's address after completion of the above attempts, document specific attempts that were made in the notification cross record log or in a donor notification form. At this time, the case is considered closed for notification purposes.
8. A log and/or records must be kept of all mailed notification letters (see example of Notification Log in Appendix D).

Information Release Form

1. Send an information release form (see example in Appendix D) to donors who request test results be sent to their physician.
 - a. When a signed and completed Information Release Request is returned, a copy of the mother/donor's test results must be mailed within 10 working days to the physician identified in the release request.
 - b. When mailing test results to the donor's physician, first class mail can be used for all test results. Stamp envelopes "Confidential" when mailing confirmed positive HIV test results via first class mail.
 - c. Copies of signed information release forms must be retained by the laboratory.

Counseling Guidelines

1. It is important to refer or to counsel donors who have confirmed positive HIV and certain genetic disease results. Provision of counseling services for other infectious disease tests and genetic screening results is optional.
2. Prior to any discussion of test results, the counselor must request and verify donor

identification. Donor identification is confirmed by the donor stating a social security number and date of birth or by presenting a federal or state picture ID.

3. Discuss the following:
 - a. Test results.
 - b. Information from the appropriate fact sheet.
 - c. The cord blood unit donation that tested positive was destroyed.
 - d. Blood donor eligibility status.
 - e. Refer donor to personal physician for further medical evaluation and follow-up, if indicated.
 - f. For donors being counseled for confirmed positive infectious disease test results, inquire about previous blood donations within the last five years. Record where and when previous donations occurred (to the best of the donor's recollection) on a separate authorization for release of test result information form (see example in Appendix D).
4. Document counseling.
 - a. Document on a Donor Counseling Worksheet (see example in Appendix D) that the above information was discussed during counseling. Include the signature of the counselor, date of counseling, and the fact that written materials were given to the donor.
 - b. Do not document further health history information (i.e., high risk behaviors) volunteered by the donor on a donor counseling worksheet. Any record of this information must be kept in the donor notification file but is not recorded on this worksheet. Keep this worksheet with the record of notification in the confidential donor notification file.
5. Mothers and infants should be referred to their physicians for further medical counseling. Clearly indicate that the mother/donor physician may call upon the CBB Medical Director for further information.
6. At the time the mother is informed of test results, provide written materials (appropriate letters, pamphlets, or fact sheets in attachments) regarding the test results as well as any applicable local support resources.

Donor Notification Records

1. The Principal Investigator of each CBB, or appropriate designee, is responsible for maintenance of a confidential file of all records associated with donor notification.

- a. Notification records may be kept in log format (see Appendix D) for hepatitis-related test results and confirmed positive syphilis test results.

At a minimum, the following information must be recorded: CBU bar code number, test results requiring notification, date of donation, date letter was sent, if letter was returned due to incorrect address, steps taken to find a correct address, and final disposition of notification, i.e., letter was sent to new address or was unable to obtain a current address.

- b. A Record of Donor Notification must be used to document all **test results for HIV**.

Confidentiality

1. Test results are considered confidential information and must be handled accordingly. Access to this information must be limited and disseminated only on a need-to-know basis.
2. Employees who have access to donor names and related test results must sign a confidentiality statement. This confidentiality agreement must be kept in the personnel files.
3. All notification records should be kept in a locked file with limited access. Cord Blood Bank procedures must state, by position title, who has access to these records.