



STEM CELL LABORATORY (STCL)



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Duke University Medical Center

Agreement for Directed Donation and Storage of Umbilical Cord Blood

1. I, _____, intend to arrange for the collection of my newborn child's umbilical cord blood, immediately following the birth of the child, and to arrange for the cord blood to be transported to Duke University (DU) for testing, freezing and storage on the terms and conditions herein set forth.
2. I, or my insurance company, have paid or made arrangements to pay to DU the processing and storage fee of \$ _____. In consideration of such payment, DU agrees it will (i) supply the collection materials to my designated collector/collection site, (ii) supply the collection site with materials and packaging for immediate shipment back to DU, (iii) receive the specimen from the collection site, (iv) test the specimen for sterility and cell counts, (v) freeze the specimen and place the specimen in a liquid-nitrogen tank for ten (10) years from date of receipt. I understand that DU does not control and cannot guarantee appropriate collection or shipment of the specimen. I also understand that DU will not perform HLA, typing or any other tests other than those specified above.
3. I agree to supply DU with (i) requested information about my newborn child; (ii) designated primary and alternate contact persons; (iii) the address and phone number for the designated primary and alternate contacts; (iv) family demographic information as requested by DU. Furthermore, I agree to notify the DU Stem Cell Laboratory, in writing and by certified mail, of my address and phone number (i) on an annual basis, and (ii) within thirty (30) days of any change of my address and telephone number.
4. DU agrees that after receiving the specimen it will continue to maintain and store the specimen in a frozen state for ten (10) years from date of receipt. Thereafter, DU will contact me to discuss continued viability of the specimen, current technologies, and agreement for the terms and conditions of storage for successive twelve month periods. If it is agreed by both parties to continue storage, in consideration for each additional year of storage I will pay in advance to DU an annual storage fee.
5. DU agrees that it will, during the period commencing on the date hereof and during any subsequent period with respect to which I have paid in advance the appropriate storage fee, upon execution by me and by any physician purporting to be licensed to practice medicine in any state in the United States or any foreign country on such forms as DU shall in its discretion request, upon not less than 45 days prior written notice to DU and upon arrangements for payment of any shipping fees, deliver to such physician the specimen which such physician requests. In no event shall DU be required to release any portion of the specimen to any person, even after my death, except as directed by me or an order of a court of competent jurisdiction.

_____ Initials

6. DU's obligations under this agreement are to act solely as custodian for the maintenance and storage of the specimen in a frozen state in accordance with the provision hereof and, subject to the provisions above I shall have rights of access to the specimen. All of my rights under this agreement and all of DU's obligations under this agreement shall terminate automatically and without further notification upon my failure to notify DU, in writing and by certified mail, within thirty (30) days of any change of my address and telephone number. All of my rights under this agreement and all of DU's obligations under this agreement shall terminate upon my failure to respond in writing and by certified mail to DU's written requests for further direction as to storage arrangements or failure to make agreed upon payments.
7. Upon the termination of DU's obligations under this agreement for any reason whatsoever, DU may dispose of the specimen by thawing and/or discarding or by use in scientific research or in any other practicable manner.
8. I agree that neither DU nor the Private Diagnostic Clinic (PDC) or any of its officers, directors, executives, physicians, partners, employees or consultants shall be liable for any destruction of, damages to or misuse of the specimen, the testing of the specimen, the freezing of the specimen, the maintenance and/or storage of the specimen in a frozen state, the improper withdrawal, thawing and/or delivery of the specimen or any other matter. Without limiting the generality of the foregoing, neither DU, the PDC or any of its officers, directors, executives, physicians, partners, employees or consultants shall be liable for any destruction, damage, misuse or improper testing, freezing, maintenance, storage, withdrawal, thawing and/or delivery caused by or resulting from any malfunction of liquid nitrogen tank, any failure of utilities, any strike, cessation of services or other labor disturbance, any war acts of the public enemy or other disturbances, any fire, earthquake, water or other acts of God, or the failure of any laboratory.
9. I understand a sample of my blood, up to 30 mL (about two tablespoons), will be taken from my arm by a registered nurse or phlebotomist. Part of this sample will be sent to a donor screening to a qualified laboratory for testing for viruses and other infections that can be transmitted through the blood, including but not limited to hepatitis B and C viruses, cytomegalovirus (CMV) virus, HTLV I and II, West Nile virus, HIV 1/2/O (the virus that causes AIDS), Zika virus, Chagas disease, and syphilis. The remainder of the sample will be saved and frozen for testing in the future for HLA typing other viruses or agents that may be carried in the blood.
10. DU will inform me of any confirmed test results that may affect my health or my baby's health. DU will offer counseling referral if needed. The law in North Carolina requires that we notify public or state health departments of confirmed positive test results for specific diseases, including HIV, HTLV, Hepatitis B, Hepatitis C and syphilis. These agencies may contact donors having confirmed positive test results. We will also notify your physician if results of these screening tests are positive. If the screening test is positive, a second more sensitive and specific test will be performed (confirmatory test). In most cases, the confirmatory test is negative. Your physician or the CCB staff will help you arrange for these tests to be done if necessary. If you do not want to be told of such results, you should not sign this consent form and you should not participate in this bank.

_____ Initials

11. I acknowledge that I understand that there is an unresolved question as to the ongoing viability and capacity of frozen umbilical cord blood and that it may deteriorate with age and that no guarantee of any kind can be made with respect to the possibility of the successful use of umbilical cord blood for transplantation by a member of my family. Except as expressly set out in this agreement, I acknowledge that neither DU nor the Private Diagnostic Clinic (PDC) or any of its officers, directors, executives, physicians, partners, employees or consultants has made any representations or warranties to me of any kind or nature, including, without limiting the generality of the foregoing, any representations or warranties with respect to (i) the viability of my child's frozen umbilical cord blood, (ii) the possibility of the successful use of my child's frozen umbilical cord blood at any time, (iii) the infallibility of DU's liquid nitrogen tanks or any other of DU's equipment at any time, and (iv) the possibility of failure of DU's liquid nitrogen tanks.
12. I acknowledge that I understand that the cord blood will not be frozen if it is received in the DU Stem Cell Laboratory after 72 hours following the baby's birth, if the volume of cord blood collected is not an adequate size for storage, or if the Director of the Stem Cell Laboratory determines the cord blood does not quality for storage for any other reason. In this event, DU will refund my storage fee.
13. It is my responsibility to notify the DU Stem Cell Laboratory of my address each year. Address notifications and changes will be sent by certified mail to:

Stem Cell Laboratory
ATTN: Barbara Waters-Pick, Lab Manager
Duke University Medical Center
2400 Pratt Street, Suite 1300
PO Box 3350, DUMC
Durham, NC 27705
Phone: (919) 668-1178
Fax: (919) 684-1555
Pager #: (800) 608-5364

14. In the event of my death I request that my specimen be

(In the event this line is blank, the specimen will be disposed of as noted in Paragraph 7 of this agreement)

15. This agreement constitutes the entire understanding of the parties and may be altered or amended only by an agreement in writing. I acknowledge that I have received a copy of this agreement. Any dispute or disagreement as to the requirements and covenants of this agreement will be resolved by binding arbitration conducted in accordance with the guidelines of the American Arbitration Association.

Signature

Date

Witness

Date

DISCLAIMER: Laboratory pricing is reviewed annually. It is possible that you may receive this contract before the annual price increases have gone into affect. Please be informed that current prices which are in affect at the time the umbilical cord blood is processed and received in the laboratory, will be billed to your account. The Stem Cell Laboratory has no control over the prices that are established annually. Pricing is based on national market analysis.

_____ Initials

Signature Manifest

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STCL-COLL-007 JA1 Agreement for Directed Donation and Storage of Umbilical Cord Blood

Author

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 May 2020, 10:48:56 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 May 2020, 10:50:28 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		21 May 2020, 02:11:22 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch (IMS19)		02 Jun 2020, 02:22:33 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		03 Jun 2020, 05:21:07 PM	Approved