Instructions for Completing the Informed Consent

Regulations that govern newborn stem cell banking require that a legal guardian and the Birth Mother (if different from the legal guardian) of the newborn donor complete the Informed Consent.

If your child’s birth involves an adoption or surrogacy:

The Informed Consent must be signed by:

- The Client, and
- The Birth Mother

The Client, as the legal guardian of the newborn, will complete the Informed Consent either by logging into the Client Web Portal at www.cbrclients.com or by signing a paper copy and returning it to Cord Blood Registry as directed below. The Birth Mother will complete the Informed Consent by signing a paper copy and returning it to Cord Blood Registry as directed below.

For all other births:

The Informed Consent must be signed by:

- The Birth Mother

The Birth Mother will complete the Informed Consent either by signing the document on the Client Web Portal at www.cbrclients.com (if given access by the Client) or by signing a paper copy and returning it to Cord Blood Registry as directed below.

Instructions for Returning Paper Forms:

Please be aware that e-mail communication can be intercepted in transmission or misdirected. Please return the Informed Consent form only by fax, registered mail, or courier delivery.

By Mail:
Cord Blood Registry  
Attention: Client Services  
1200 Bayhill Drive  
San Bruno, California 94066

By Fax:
1-800-844-2202  
See facsimile cover sheet on next page
TO: CBR Client Services
FROM: ____________________________

CBR FAX: 1-800-844-2202
DATE: ____________________________

CBR TEL: 1-800-588-6377
YOUR PHONE: ____________________________

RE: Enrollment forms
ACCOUNT #: ____________________________

PAGES: ________
CLIENT NAME: ____________________________

The information contained in this message may be privileged and confidential. If you are NOT the intended recipient, please notify the sender immediately and destroy this message.
Shortly after your baby is delivered, and the umbilical cord is cut, excess blood remains in the umbilical cord and the placenta. This blood is rich in hematopoietic (blood-forming) stem cells that can be used to treat an adult or child with certain life-threatening conditions. Use of cord blood stem cells in regenerative medicine therapies is under evaluation. To collect the cord blood, the umbilical cord is cleaned and accessed with a needle attached to the CBR CellAdvantage® newborn stem cell collection bag. The blood remaining in the placenta and umbilical cord drains by gravity into the collection bag. As the blood is draining, there is no risk to the mother or the baby. There is no change in the actual delivery process. Cord blood can be collected after a vaginal or cesarean delivery.

The umbilical cord itself (cord tissue) contains a large number of mesenchymal stem cells, which are being researched as treatment for a number of conditions. To collect cord tissue, the healthcare provider cuts a 4-8 inch segment of cord tissue and places it into the CordCup® container. After the cord blood and cord tissue are collected, they are returned to the CBR CellAdvantage Newborn Stem Cell Collection Kit and sent to CBR’s laboratory for testing, processing and storing. Cord tissue will require additional processing prior to use in medical treatment.

Although infrequent, complications may occur during birth that preclude the collection of newborn stem cells or affect the quality of the sample. Therefore, collection of newborn stem cells cannot be guaranteed. Your health and the health of your baby are your healthcare provider’s first priorities. You agree that your healthcare provider’s judgment is absolute and final. You agree to not hold your healthcare providers, hospital/birthing center, and its affiliates or its or their directors, officers, employees or agents responsible for the collection or failure to collect cord blood or cord tissue or for the handling of cord blood or cord tissue.

CBR will perform tests on the cord blood unit (including cell viability, total cell number, blood typing) to determine the nature and quality of the cord blood unit. The birth mother will provide a sample of blood that will be tested for certain infectious diseases including HIV, syphilis, hepatitis, and other viruses. The testing requirements for cord blood and the maternal blood draw will be updated periodically as required by various regulatory and testing agencies.

The birth mother will authorize disclosure of these test results in connection with the release of the stem cells. Without this authorization, it may not be possible to use the stem cells in medical therapies. Test results may be reported to the birth mother, her physician, the baby’s physician and legal guardians, a transplant physician or agent (if applicable) and to governmental regulatory agencies as required by law. Infectious disease tests are not always accurate and may give false positive results. Test results may be used for research or in publications so long as they are aggregated and do not contain donor information. Due to regulatory requirements, the absence of a maternal blood sample or the failure to adequately test maternal blood may preclude the stem cells from being used in medical therapies. The risks involved with giving a blood sample include bruising, redness, pain or discomfort, or inflammation around the needle insertion site.

The birth mother will answer a detailed questionnaire about her medical condition and the baby’s potential exposure to infectious disease. The birth mother will authorize disclosure of this questionnaire in connection with the release of the stem cells. Without this authorization, it may not be possible to use the stem cells in medical therapies.

The stem cells may be used by the child or a first or second degree relative. Cord blood stem cells are not the treatment of choice for all diseases or conditions. The decision to use cord blood stem cells should be made in consultation with the attending physician. There are some diseases for which a person’s own stem cells may not be usable for treatment. In addition, some diseases may be treatable by one person’s stem cells but untreatable by a different person’s stem cells.
Treatment using cord blood stem cells may not be effective. In the future, better therapies may be developed. Treatments using cord tissue stem cells are being researched. There is no current treatment that uses cord tissue and there is no guarantee that cord tissue will now or in the future be able to treat any disease or condition.

The cord blood and cord tissue will be a perfect match for the child and may or may not be an acceptable match for siblings and other family members. There are factors (including, but not limited to, HLA type, contamination, and cell count) that may impact the utility of the sample(s), as determined by the treating physician. The success of a stem cell transplant depends on many factors unrelated to the cord blood or cord tissue, including the degree of match between the donor and recipient, the condition of the recipient, and the type of condition being treated.

The newborn donor has property rights in the cord blood and cord tissue samples. Until the child’s eighteenth birthday, the child’s parent or legal guardian controls the use of the newborn stem cells. Once the child turns eighteen years old, the child controls the use of the newborn stem cells.

A client in good standing (i.e., whose account is current) may instruct CBR in writing to transfer or discard the newborn stem cells. Upon receipt of such request, CBR will inform the client of the requirements for transfer or destruction. Additional fees may apply. If the client’s account terminates without instructions for the disposition of the newborn stem cells, ownership will transfer to CBR and the cells may be used for quality control and testing purposes.

CBR HAS NO LIABILITY OF ANY KIND IN RESPECT OF CBR’S PERFORMANCE OR FAILURE TO PERFORM UNDER THIS AGREEMENT EXCEPT TO THE EXTENT ATTRIBUTABLE TO CBR’S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT. IN NO EVENT SHALL CBR’S LIABILITY EXCEED THE TOTAL AMOUNT PAID BY CLIENT TO CBR UNDER THIS AGREEMENT. CBR SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES IN RESPECT OF BREACH OF CONTRACT, WARRANTY, STRICT LIABILITY OR TORT), WHETHER OR NOT CBR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS PARAGRAPH SHALL APPLY NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

CBR shall not be responsible for procedures or services performed by third parties, including, but not limited to, sample collection, lab testing, Courier Transport, improper handling, or use during transplantation or medical procedure.

You can withdraw consent for procurement and it will not affect your or your baby’s access to medical care. You agree that you have been given the opportunity to ask questions and your questions have been answered satisfactorily.

CBR has developed a privacy policy that governs how CBR collects, uses, discloses and stores your information. Please read the privacy policy at www.cordblood.com/privacy to understand how your information will be treated. CBR may from time to time amend this Privacy Policy. If CBR makes material changes to this Policy, CBR will post the revised Policy and the revised effective date on the website.

Required disclaimer for New York residents: Specific to Cord Tissue: CBR’s activities for New York State residents are limited to collection of umbilical cord tissue and long-term storage of umbilical cord-derived stem cells. CBR’s possession of a New York State license for such collection and long-term storage does not indicate approval or endorsement of possible future uses or future suitability of these cells.

_______________________________________________  _____________________________________________  ______/_____/_____
Name                                              Signature                                               Date

Please note: Your hospital may require a copy of this form (Sections 1 and 2) upon admission.