Newborn Possibilities Program® Application
(Low Apgar/Prenatal Diagnosis Protocol)

SECTION 1 - AGREEMENT
This Agreement is between you and Cbr Systems, Inc. (“Cord Blood Registry” or “CBR”) for newborn stem cell preservation services. You are electing to preserve cord blood and cord tissue. Cord tissue will require additional processing prior to use in medical treatment. In this Agreement, cord blood and cord tissue are called “newborn stem cells” or “sample.”

Cord Blood Registry® (CBR®) offers the Newborn Possibilities Program (NPP) Program to newborns in the United States who have an increased likelihood of using their newborn stem cells in emerging clinical trials and/or experimental applications. If eligible, CBR will supply the collection kit and will process and store your newborn’s cord blood and cord tissue free of charge. A cord blood collection of < 20mL (about two tablespoons) will not be eligible for free processing and storage under the terms of the program. CBR is not responsible for additional fees charged by your caregiver or hospital associated with the collection of your newborn’s cord blood and cord tissue. CBR will cover the cost of One-Step Shipping™ of the collection kit from the hospital to our laboratory at the then-current price. Upon receipt, of this completed application, CBR will attempt to notify you of your approval status within five business days.

CBR will store the cord blood and cord tissue free of charge for 60-months. During this 60-month period, the banked cord blood and cord tissue remain the sole property of CBR but will be designated for therapeutic use by the newborn (fill in name below, if known).

At the end of 60 months, you may choose to extend storage by converting to Family Banking and will be responsible for all subsequent annual storage fees at their then-current price. Family Banking is subject to the terms and conditions in effect at the time of conversion. CBR may contact you periodically to ask for medical updates on the newborn.

1. Collection of the Newborn Stem Cells
CBR will provide you with a CBR CellAdvantage® Newborn Stem Cell Collection Kit to collect and transport the newborn stem cells. You will request that your healthcare provider collect the newborn stem cells. You agree to follow the instructions provided by CBR and your healthcare provider. Your healthcare provider does not act as an agent of CBR.

2. Transport of the Sample(s)
You will arrange or have arranged for express shipment of the newborn stem cells to CBR’s laboratory. You may use CBR’s One-Step Shipping, which uses next-flight-out shipping, or another courier of your choice. CBR has no responsibility or liability for third-party courier transport of the sample(s) to CBR’s laboratory, including for One-Step Shipping.

3. Testing, Processing, and Storage of the Sample(s)
After CBR receives the CellAdvantage kit, CBR will test, process, cryopreserve, and store the newborn stem cells. CBR will also test the birth mother’s blood sample for HIV, hepatitis, syphilis, other infectious conditions required by regulatory agencies, and as needed to determine the suitability of the sample for storage. CBR reserves the right to reject and discard any samples in accordance with its standard operating procedures if the test results indicate the sample(s) do not meet CBR’s standards or minimum requirements for storage. CBR does not store samples associated with positive HIV test results.

4. Understanding Your Rights to the Sample(s)
You agree that you are the child’s legal guardian and understand that CBR will treat you as the sole designated contact for all purposes relating to this Agreement, including but not limited to retrieval and use of the sample, access to your account, updates to contact information, and termination of this Agreement. In the event that you wish to assign your rights and/or obligations under this Agreement to a third party, both the third party and CBR must agree in writing.

During the 60-month storage period, the sample remains the sole property of CBR but is designated for the individual listed above. After the storage period, the sample remains the sole property of CBR and may be used for quality control or testing, unless you convert to Family Banking.

5. Requests for Retrieval of the Sample(s)
Requests for retrieval must be made in accordance with CBR’s procedures at the time. CBR can ship a sample only to an entity that can receive a sample in compliance with all applicable rules and regulations.

6. Term and Termination
This Agreement is effective upon your assent. If you are not the birth mother, the birth mother must also agree to the Informed Consent and complete the Medical Health and History Profile.

You may terminate this Agreement at any time by notifying CBR and following the procedures in place at that time. If you are no longer the child’s legal guardian, CBR will send written notice to the legal guardian of the cancellation. The legal guardian will have thirty (30) days to agree to take on all the rights and obligations under this Agreement. If the legal guardian fails to agree within such period, then the Agreement will terminate. If the legal guardian provides his or her agreement within such period, then the Agreement shall continue with the legal guardian succeeding to all of your rights and obligations under this Agreement.

Any expiration or termination of this Agreement is without prejudice to any rights, claims, or causes of action that may have accrued prior to such expiration or termination.

7. Notification of Account Changes
At all times while this Agreement remains in effect, you shall promptly notify CBR of changes to your and the child’s contact information. CBR is entitled to rely on the contact information on file that you have provided.

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8. Indemnification
You agree to indemnify and hold harmless CBR and its affiliates, shareholders, directors, officers, agents, or employees from loss, cost, or damage arising from any claim, liabilities, demands, and causes of action made or brought by any person, including the child or other legal guardian of the child, relating to the sample(s).

9. Warranty Disclaimer
You acknowledge and agree that neither CBR nor any of its shareholders, directors, officers, agents, employees, or affiliates have made any representation, guaranty or warranty, express or implied, to you of any kind. You acknowledge and agree to the following specific disclaimers:

There is no guarantee or assurance regarding success in collecting newborn stem cells. Complications may occur during birth that preclude the collection of the newborn stem cells. The collection of cord blood and/or cord tissue cannot be guaranteed by CBR, as the collection is arranged between you and your healthcare provider. You acknowledge that your healthcare provider makes the final determination whether or not to collect the newborn stem cells. Eligibility for storage cannot be fully assessed until the arrival and evaluation of a sample at CBR’s laboratory. CBR maintains the right to reject or discard any samples in accordance with our standard operating procedures due to certain test results or lack of test results.

There is no guarantee that the newborn stem cells will not deteriorate or suffer another form of loss. There is no guarantee that the newborn stem cells will be of therapeutic value. You acknowledge that the child or other family member may never use the newborn stem cells. No courier transport service can be one hundred percent reliable and, on occasion, some samples may be delayed, lost, or damaged in transit.

10. Limitation of Liability
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 THE 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.

CBR shall not be responsible for procedures or services performed by third parties, including, but not limited to, collection, lab tests, courier transport (including any One-Step Shipping courier), improper handling, or use during transplantation.

11. Assignment and Delegation
CBR may assign its rights and delegate its obligations under this Agreement to any successor by merger or consolidation, to any purchaser of all or substantially all of CBR’s assets relevant to the performance of the services to be provided by CBR hereunder, or to any person that provides services similar to those that are to be provided by CBR hereunder or who intends to provide such services following any such assignment or delegation. CBR may perform services to be provided by it hereunder through subcontractors. This Agreement is not assignable by you without the prior written consent of CBR and any attempted assignment in breach of the foregoing restriction shall be void.

12. Governing Law
This Agreement shall be governed by and construed in accordance with the laws of the State of California. Any dispute or controversy arising between or among you, the child, and CBR shall be finally and conclusively resolved by binding arbitration following the rules provided in Title 9 of the California Code of Civil Procedure. In the event of arbitration or any court proceedings, the court or arbitrator may award reasonable attorneys’ fees and costs to the prevailing party in addition to any other relief to which the party is entitled.

13. Entire Agreement
This Agreement, together with the Informed Consent, constitutes the entire Agreement between the parties and supersedes all previous agreements or representations by CBR, oral or written, relating to the subject matter of this Agreement.

14. Force Majeure
If CBR’s performance of this Agreement is prevented, restricted, or interfered with by reason of fire, earthquake, or other casualty or accident; strikes or labor disputes; war or other violence; any law, order, proclamation, ordinance, demand, or requirement of any government agency; or any other act or condition beyond the control of CBR, then CBR shall be excused from such performance.

15. Severability
If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall nevertheless continue in full force without being impaired or invalidated in any way.

16. General
This Agreement shall be binding on you and CBR and your and its heirs, personal representatives, successors, and permitted assigns.

This Agreement may only be modified or amended by a writing signed by each party.

Both you and CBR acknowledge they have read this Agreement, understand its terms and conditions, and intend to be legally bound by it.

Signature of applicant: ______________________________
Name of applicant: ______________________________ Date: ___ / ___ / ______
First Name   Middle Name      Last Name
mm  dd  yyyy

Important Instructions
Please read the instructions below. If you have any questions, please contact your Cord Blood Education Specialist at 1-800-588-6377.

To apply: 1. Please have the patient’s obstetrician or treating physician complete and sign the Newborn Possibilities Program Application Part 2.

2. Fax or mail the completed Newborn Possibilities Program Application (sections 1 through 4) as soon as possible after birth for review of eligibility.

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SECTION 2 – AGREEMENT

Please print clearly and answer all questions

Name of applicant (expectant mother or parent): __________________________________________________________________________________________

Address: __________________________________________________________________________________  Telephone: (_______) _____________________

Health Insurance: ___________________________________________________________________________________________________________________

Please complete and follow the instructions below for Prenatal Diagnosis Protocol or Low Apgar Protocol.

Prenatal Diagnosis Protocol Applicants
A copy of the medical record documenting the prenatal diagnosis must be sent to CBR with this application.

Prenatal diagnosis of newborn:
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

Low Apgar Protocol Applicants
If prior documentation of the Apgar score and/or physician notes have been submitted to CBR, the Apgar score and physician signature are not required at this time.

Newborn Apgar score:
____ 1 minute  ____ 5 minutes  ____ 10 minutes

If applicable, documentation of suspected reason for artificially elevated Apgar score (i.e., >3 at 5 minutes):
________________________________________________________________________________________
________________________________________________________________________________________

Obstetrician or treating physician name: __________________________________________________________________________________________________

Practice/hospital name: _______________________________________________________________________________________________________________

Address: ___________________________________________________________________________________________________________________________

City: ______________________________________________________________________ State: __________________ ZIP: _____________________________

Obstetrician or treating physician signature: _______________________________________________________

Date: _________ / _________ / _____________

CBR Office Use Only

☐ Application Approved  ☐ Application Denied

Reason denied: __________________________________________________________________________________________
________________________________________________________________________________________

Reviewed by: ________________________________________________________ Date: ____ / ____ / _______

mm   dd   yyyy

— Continue —
SECTION 3 – INFORMED CONSENT

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. 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. The cord tissue will be collected after the cord blood collection is performed. 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.

The birth mother will answer a detailed questionnaire about her medical history and the baby’s exposure to infectious disease. The birth mother will authorize disclosure of this questionnaire and infectious disease marker 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. The test results may be aggregated and used in publications without donor identification.

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.

You understand that you can withdraw consent for procurement and it will not affect you 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.

**Required disclaimer for New York residents:**
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.

Signature of applicant: _______________________________________________________________ Date: ________ / ________ / __________

mm                               dd                              yyyy

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SECTION 4 – MEDICAL AND HEALTH HISTORY PROFILE

A Medical and Health History Profile is required by regulatory agencies. Please complete the information below to the best of your knowledge.

Mother’s Full Name: _______________________________  Father’s Full Name: _______________________________

Social Security #: _____________________________  Social Security #: _____________________________

Date of Birth: __________ / __________ / __________  Date of Birth: __________ / __________ / __________

Address: ____________________________________________  City: ___________________________  State: __________  Zip: __________  Country: __________

Home Phone: (__________) __________ – __________  Cell Phone: (__________) __________ – __________

Email (Primary): ________________________________  Email (Secondary): ______________________________

Expected Due Date: __________ / __________ / __________  Maiden Name: ________________________________

Emergency Contact: __________________________________________  Phone: (__________) __________ – __________

Primary OB/Midwife Name: ________________________________  Office Phone: (__________) __________ – __________

Office Address: __________________________________________  City: ___________________________  State: __________  Zip: __________  Country: __________

Health of mother:

Are you in good general health?  Yes  No

Are you currently taking an antibiotic or other medication for an infection?  Yes  No

In the past 12 months, have you or the baby’s father:

Had body piercing, tattoo, accidental needle stick, or unprotected contact with someone else’s blood?  Yes  No

Been incarcerated in a correctional facility for more than 72 hours?  Yes  No

Been diagnosed with or exposed to tuberculosis or been in a malaria endemic country?  Yes  No

Lived with or had sexual contact with anyone who has been diagnosed with hepatitis?  Yes  No

Had sexual contact with someone who is HIV positive?  Yes  No

Had sexual contact with someone who takes money, drugs, or other payment for sex?  Yes  No

Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?  Yes  No

Had sexual contact with a male who has ever had sexual contact with another male?  Yes  No

In the past 12 months, have you (mother only):

Had or been treated for syphilis, gonorrhea, or other sexually transmitted disease?  Yes  No

Had a blood transfusion or tissue graft such as bone or skin?  Yes  No

Had a West Nile virus infection?  Yes  No

In the past 6 months, have you (mother only):

Received a bite from an animal suspected of rabies?  Yes  No

In the past 8 weeks, have you (mother only):

Had any vaccinations or other shots (excluding Rhogam and/or the seasonal flu shot)?  Yes  No

Had close contact with someone who received a smallpox vaccination?  Yes  No

Please explain or clarify any “yes” answers:

__________________________________________________________________________________________

__________________________________________________________________________________________

Date: __________ / __________ / __________

Client Signature

__________________________________________________________________________________________

Date: __________ / __________ / __________

Medical Director or Designee (for CBR personnel only)

From 1980 through 1996 (mother only):

Did you spend a total time of three (3) months or more in the United Kingdom?  Yes  No

Were you stationed overseas as a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?  Yes  No

From 1980 to the present, did you (mother only):

Spend time that adds up to five (5) years or more in Europe?  Yes  No

Receive a blood transfusion in the United Kingdom or France?  Yes  No

Have you ever (mother only):

Received human pituitary growth hormone?  Yes  No

Received a dura mater graft or organ/bone marrow transplant?  Yes  No

Had or been treated for malaria, Chagas disease, babesiosis, or other parasitic disease?  Yes  No

Had or been treated for syphilis, gonorrhea, or other sexually transmitted disease?  Yes  No

Chronically abused drugs or alcohol?  Yes  No

Had a significant exposure to a toxic substance (such as lead or mercury)?  Yes  No

Have you or the baby’s father ever:

Received money, drugs, or other payment for sex?  Yes  No

Used needles to take drugs, steroids, or anything not prescribed by your doctor?  Yes  No

Been in Africa or had sexual contact with anyone who was born in or lived in Africa?  Yes  No

Been turned down as a blood donor?  Yes  No

Been diagnosed with or had a relative diagnosed with Creutzfeldt-Jacob disease?  Yes  No

Used clotting factors for a bleeding disorder such as hemophilia?  Yes  No

Been a recipient of xenotransplantation (animal to human transplant)?  Yes  No

Have you or the baby’s father ever:

Tested positive for hepatitis B?  Yes  No

Tested positive for hepatitis C?  Yes  No

Tested positive for HIV/AIDS virus?  Yes  No

Tested positive for HTLV-I or II?  Yes  No

- Continued -
AUTHORIZATION TO RELEASE PERSONAL HEALTH INFORMATION
(To be completed by the biological mother)

You are being asked to sign this authorization form to permit CBR to disclose certain personal health information about you and/or your child.

By signing this form, you authorize CBR to disclose to your child, your child's physician, your child's legal guardian, your physician, and the transplant recipient's physician (if applicable) the following information:

- The completed Medical Health and History Profile
- The results of the tests performed on the maternal blood draw
- The results of the tests performed on the cord blood and cord tissue
- Any medical data that you have disclosed to CBR about you or your child

Your personal health information may be used and/or disclosed for the evaluation of or performance of a transplant or infusion of the newborn stem cells.

Your authorization covers disclosures made at your request, at your child's request (once the child reaches eighteen years of age), and at the request of your child's legal guardian (if this is someone other than you). It also covers requests made by the physicians of you, your child, your child's legal guardian, and the transplant recipient.

You have a right to refuse to sign this authorization. However, regulations governing cord blood transplantation and medical procedures require the release of this information to the physician performing the procedure. Therefore, signing this form is a required part of the CBR enrollment process.

You have a right to revoke this authorization at any time by notifying CBR in writing at:

Cbr Systems, Inc.
Attn: Scientific and Medical Affairs
1200 Bayhill Drive
San Bruno, California 94066

Your refusal to sign or your decision to revoke your authorization will not affect any disclosure of information that CBR may have made prior to CBR’s receipt of your revocation. A copy of the signed authorization form will be provided to you by CBR upon your request.

This authorization will expire upon the release of the cord blood and cord tissue sample(s) by CBR.

You authorize CBR to use all information and test results obtained by CBR without restriction provided that confidentiality is maintained and data blinded.

You understand that personal information used or disclosed pursuant to this authorization may be re-disclosed by the recipient and its confidentiality may no longer be protected by federal or state law.

Signature of applicant: _________________________________________________________________  Date: ________ / ________ / __________

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