

APPENDIX B

SAMPLE INFORMED CONSENT FORM

B.1 INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Umbilical Cord Blood Banking for Transplantation

You are being asked to take part in a research study that is trying to find better ways to treat patients with leukemia, bone marrow failure, and certain rare inherited diseases (for example, immune deficiency, inborn errors of metabolism, and storage diseases). Before agreeing to join the study, you need to understand the purpose of the study and what you will be asked to do. This process is called informed consent.

This is an informed consent form and it gives details about the study. Once you have had a chance to read this form and discuss the study with your doctor, you will be asked to sign the form if you wish to take part. You will also be given a copy of the form.

Purpose of the Study

Blood cells produced by a baby before birth circulate through the baby's body, umbilical cord, and placenta. These blood cells bring oxygen and nutrition from the mother's blood to the baby. When the baby is born, the umbilical cord is cut and the baby is separated from the placenta and the mother. The placenta, or "afterbirth," is delivered several minutes later and is usually thrown away. The placenta contains one-third to one-half of a cup of blood which is rich with blood cells. These blood cells could be used to replace the blood cells in a person who has leukemia, bone marrow failure, or a certain rare inherited disease. The replacement process is called transplantation.

Insert Banking Program Name Here has a program to collect the usually discarded blood cells from the placenta and umbilical cord and use them as blood cells for transplantation or for research.

Your Involvement in the Study

By volunteering to take part in this study, you are agreeing to do the following things:

1. Allow the blood from the umbilical cord and placenta taken after your baby's delivery to be tested and frozen for research. If our tests show that the cord blood is suitable for transplantation, it will be stored until it is given to a person who needs a bone marrow transplant or until it is no longer suitable for storage.

If the cord blood is not suitable for transplantation, it may be thrown away using standard hospital practices or it may be used in laboratory research that has been approved by *Insert IRB Name Here*, an institutional review board. The cord blood will not be cloned or used for any commercial purpose. Cord blood used in laboratory research will not be used for transplantation. If it is used for research, your identity and your baby's identity will not be known.

2. Allow a sample of the cord blood to be tested for some genetic diseases that can be passed through blood cells, like Gaucher's Disease and Adrenoleukodystrophy (ALD). The tests are

done to protect the person who will eventually receive the cord blood.

Allow an additional sample of cord blood to be frozen and stored for future testing for such infectious diseases as hepatitis, cytomegalovirus (CMV), HTLV I and II, and HIV (the virus that causes AIDS). These tests will only be done if the cord blood is selected to be used in a transplant.

All test results are confidential. Any test performed will be done for the safety of patients who may receive the cord blood. We will try to inform you of any confirmed positive test results which may affect your health or your baby's health. We will offer a counseling referral if needed. If you do not want to be told of these test results, you should not sign this consent form or take part in the study.

3. Allow a sample of the cord blood to be tissue typed. Tissue typing gives a "fingerprint" of the blood cell by analyzing the cell DNA. This DNA fingerprint will be needed to match the cord blood cells to a patient's blood cells.
4. Give up to 30 mL (about two to three tablespoons) of your blood. The blood will be taken from your arm by a qualified person and tested for viruses such as hepatitis, cytomegalovirus (CMV), HTLV I and II, HIV (the virus that causes AIDS), and syphilis. The tests will be used to find out if the cord blood can be stored in the cord blood bank. The testing may include tissue typing (DNA fingerprinting) of the cells. Some of the blood will be frozen and stored for future testing if tests become available for currently unknown diseases.

All test results are confidential. Any test performed will be done for the safety of patients who may receive the cord blood. We will try to inform you of any confirmed positive test results which may affect your health or your baby's health. We will offer a counseling referral if needed. If you do not want to be told of these test results, you should not sign this consent form or take part in the study.

Insert as Appropriate:

The law in *Insert State Name Here* requires that we give the names of persons who test positive for certain diseases to public or state health agencies of confirmed positive test results for certain diseases, including HIV and syphilis. These agencies may contact you if you have confirmed positive test results.

5. Answer questions about your and your family's medical history, including questions about your pregnancy, drugs you are taking, and past medical problems in your family and in the father's family. There are also questions about your current and past lifestyle, including sexual history and drug use. These questions are similar to questions asked when a person donates blood. The information is confidential and will be used to find out if the cord blood can be stored in the cord blood bank.
6. Allow your and your baby's medical charts to be reviewed, specifically for pregnancy and delivery information and hospital tests up to the time of your discharge from the hospital.

7. Allow your baby's blood screening test results to be checked. The tests look for diseases such as Sickle Cell Anemia and Thalassemia, and are required by the state of California/North-South Carolina.

Insert as Appropriate:

8. Allow us to contact you (about six months and one year after your baby's birth) to ask about any changes in your baby's health which might affect the cord blood's suitability for transplantation. Our contact will coincide with the regular "Well Baby" check-ups that should be a part of routine care for all babies at two months, six months, and one year of age. We may ask for your permission to contact your pediatrician or family doctor at these times.

Possible Risks and Discomforts

Taking blood from your arm for tests may cause bruising, infection, fainting, pain, or discomfort. All normal precautions will be taken to keep these side effects from happening.

We will make every effort to protect your and your baby's confidentiality. In the rare event your identity becomes known, a transplant patient could try to contact you.

In the rare event your name and positive test results (for example, HIV tests) became known, you could be treated unfairly by others.

Anticipated Benefits to You and Your Baby

There will probably be little or no direct benefit to you or your baby from taking part in this study. However, it is possible that our tests will detect an infection or genetic disease which would affect you or your baby and which might not have been otherwise detected. This early detection could result in earlier treatment and improved health care.

If, in the future your child needs a bone marrow transplant and the cord blood was banked and still available, it could be used for your child. It is also possible that your baby's blood will match a brother's or sister's blood if a transplant is ever needed. Keep in mind, though, if the cord blood has already been given to another person for transplant, it will not be available for your child or children.

Another benefit to you and your family is the satisfaction of potentially helping others.

Anticipated Benefits to Society

Currently, many patients who need a transplant cannot find a donor. The cord blood bank will provide another source of donor blood cells, allowing more people the chance to receive a potentially life-saving transplant.

Alternatives to Participation in This Study

There are companies who collect, process, and store cord blood for family use only. They charge a fee for this service. If you choose to use one of these companies to store your baby's cord blood, you

should contact them immediately to make the arrangements. If you decide to use one of these companies, you will not be allowed to take part in this study.

You may also choose not to take part in this study. If you decide not to take part, the cord blood will be thrown away using standard hospital practices.

Financial Obligation

You will not be charged and there will be no cost to your insurance company for anything connected to this study. You will not be paid for taking part in this study.

Privacy and Confidentiality

No information identifying you or your baby will be given to anyone unless required by law or unless you request that the information be given. A Certificate of Confidentiality has been obtained for this study. The purpose of this certificate is to prevent any and all persons not connected with the study or courts from gaining access to your identity.

Information collected in this study will be reported to the National Heart, Lung and Blood Institute, the Food and Drug Administration, the International Cord Blood Transplant Registry, and the scientific community. Your name and your baby's name, or any other identifying information, will not be included in any study reports or papers.

Information collected in this study will be reviewed by authorized officials from the National Heart, Lung and Blood Institute, the Medical Coordinating Center (The EMMES Corporation), the Food and Drug Administration, or other agencies. Access to study information by these individuals will be provided under a guarantee of confidentiality and only for the purpose of making sure that this study is following proper procedures.

Participating In and Withdrawing From the Study

If you choose to take part in this study, your participation is voluntary. You are also free at any time to stop participating in the study, without any effect on your future care at *Insert Banking Program/Parent Medical Center Name Here*. If you choose not to take part in the study, this decision will not affect your or your baby's right or access to health care or other services which you are entitled to receive at *Insert Banking Program/Parent Medical Center Name Here*.

Your baby's cord blood cannot be withdrawn from the study after it has been released to a patient for transplant.

Withdrawal by the Investigator

There is no guarantee that your cord blood will be collected or stored. There are many reasons why this could happen.

Blood may not be collected because the collection team is not available or because the baby's birth is

complicated with fever in the mother, early rupture of membranes, mixing of the mother's and baby's blood, or a birth defect or genetic disease in the baby.

Blood may not be stored because the amount of cord blood collected is too small, the cord blood is infected, or there are problems in the processing or freezing of the cord blood.

In addition, there is always the possibility that an unexpected problem may arise and result in the cord blood not being collected or stored.

You will not be told whether or not the cord blood is stored unless you request to be told. You can contact us at _____ (Address) or _____ (Phone Number).

Identification of Investigators

If you have any questions about this study, feel free to contact _____ (Name of Bank Director and/or Medical Director) at _____ (Address) or _____ (Phone Number).

Rights of Research Subjects

At any time, you may withdraw your consent and end your participation in this study without a penalty. If you have any questions about your rights as a research subject, you may contact the Office for Protection of Research Subjects at _____ (Address) or _____ (Phone Number).

VOLUNTEER DONOR INFORMED CONSENT FOR CLINICAL RESEARCH

Title:

Umbilical Cord Blood Banking for Transplantation

Purpose:

The purpose of this study is to collect and store umbilical cord blood and use it to replace the blood-forming cells in a person with a serious blood disease.

Signature of Research Subject:

I have read and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form as well as a copy of the Subject's Bill of Rights.

By signing this form, I willingly agree to participate in the research it describes.

Name of Subject

Signature of Subject

Date

Signature of Investigator or Designate:

I have explained the research to the subject and answered all of her questions. I believe that she understands the information described in this document and freely consents to participate.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date
(must be same as subject's)

Signature of Witness:

My signature certifies that the subject has signed this consent form in my presence as her voluntary act and deed.

Name of Witness

Signature of Witness

Date
(must be same as subject's)

B.2 PRELIMINARY INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Umbilical Cord Blood Banking for Transplantation

You have asked if you could donate your baby's cord blood to the *Insert Cord Blood Bank Name Here*. We welcome your donation, but because you will deliver your baby soon, we do not have time to tell you everything you need to know to make an informed decision about participation in this research project before the birth of your baby.

Since cord blood must be removed from your placenta (afterbirth) within 10-15 minutes of your baby's delivery, we will streamline the process of obtaining your consent for collection by having you read and sign this short form before the birth of your baby. We will attempt to collect your baby's cord blood and if the collection is successful, we will provide you with detailed information about the program and obtain complete consent within 12-48 hours of your baby's birth.

By signing this informed consent form you are agreeing to the following:

1. You wish to donate your healthy baby's umbilical cord blood to the *Insert Cord Blood Bank Name Here* at *Insert Institutional Name Here*, and you give your permission for a Collection Specialist to collect the cord blood from the placenta and cord shortly after delivery.
2. You understand that if a sufficient volume of cord blood is collected for processing and banking, a Collection Specialist will come and talk to you about the study in detail before you are discharged from the hospital. At that time the Collection Specialist will explain the program to you, have you sign a long consent form, and take a complete medical history from you. If you do not sign the long consent form, the cord blood will not be saved.
3. You agree to allow a nurse to take a little extra blood (20-30 ml, about one to two tablespoons) at the same time she draws blood as part of your medical care for admission to Labor and Delivery.
4. You understand that if the volume of cord blood collected is insufficient for processing and banking, it may be used for research projects at *Insert Institutional Name Here*. If this occurs, no further consent will be done and you give permission for the use of your baby's cord blood for research by signing this form. The cord blood will not be cloned or used for any commercial purpose.

You will not be charged and there will be no cost to you or your insurance company for anything connected to this study. You will not be paid for taking part in this study.

You are also free to stop participating in the study at any time. If you choose not to take part in the study, or to stop participating, this decision will not affect your or your baby's right or access to health care or other services which you are entitled to receive at *Insert Institutional Name Here*.

By signing this form, you willingly **agree to participate**. If you have any questions about this study,

please contact _____ (*Principal Investigator*), Director of the _____
(*Name of Cord Blood Bank*), at _____ (*Address*) or _____
(*Phone Number*).

Name of Mother

Signature

Date

Name of Person Obtaining Consent

Signature

Date