

APPENDIX A
SAMPLE CONSENT FORM

CORD BLOOD TRANSPLANTATION STUDY EXPANDED ACCESS PROTOCOL

CORD BLOOD TRANSPLANTATION (COBLT) STUDY

**SAMPLE CONSENT FORM
FOR THE EXPANDED ACCESS PROTOCOL**

You (your child) are being asked to take part in a clinical research study. Clinical research tries to find better ways to diagnose and treat disease. Taking part in any clinical research involves risks and benefits. You need to understand these risks and benefits to make an informed decision about whether or not to join the study. This process is known as informed consent.

This consent form gives detailed information about the research study that your doctor will discuss with you. Once you understand the study, you will be asked to sign this form if you wish to take part. You will have a copy to keep as a record.

The research study you are being asked to join is:

**CORD BLOOD TRANSPLANTATION (COBLT) STUDY EXPANDED ACCESS
PROTOCOL**

PURPOSE OF THE RESEARCH STUDY

The purpose of the study is to provide a suitably matched cord blood unit to a person who is eligible for a cord blood transplant, but is not eligible for the COBLT Study Transplantation Protocol.

You (your child) have a serious or life-threatening condition. You (your child) have reviewed all treatment options available to you with your doctor. An acceptable treatment for this condition is an umbilical cord blood transplant on a clinical study using a cord blood unit collected on the COBLT Study.

Your (your child's) doctor has described the clinical study procedures, treatment, and side effects of cord blood transplantation to you (your child). You (your child) have already signed a separate consent document agreeing to take part in the clinical study.

As part of the COBLT Study Expanded Access Protocol, you will be asked to supply a blood sample for future HLA typing studies. These studies will not directly benefit you (your child) but will hopefully benefit patients in the future.

ALTERNATIVE TREATMENTS

The other options potentially available to you are autologous (self) transplantation, a bone marrow transplant from an unrelated donor, a bone marrow transplant from a family member who has a different tissue type (HLA- type), chemotherapy, or no therapy other than supportive care. Each option will be fully explained to you.

CORD BLOOD TRANSPLANTATION STUDY EXPANDED ACCESS PROTOCOL

In a recent review of the outcomes of 65 adults on COBLT studies undergoing cord blood transplantation for advanced leukemia and other diseases with poor prognoses, only 15% of the patients were alive at one year after transplantation.

You will be informed of the progress of this research study. During the time you are part of it, you will be informed of any new findings which might affect your willingness to continue.

BENEFITS

Although it is our hope that this research study will be of benefit to you (your child), and that it will help other patients, we cannot say that it will be directly beneficial to you (your child).

FINANCIAL COST

You will not be responsible for any costs associated with the shipping or testing the cord blood unit (unless you have a metabolic disorder and will be using a non-COBLT unit). You will be responsible for hospitalization, physician's visits, and established diagnostic laboratory tests and the chemotherapy drugs, radiation therapy, and other medicines used in your care. These costs will be the same as for any other bone marrow transplant patient. Further, your (your child's) financial responsibility for this treatment will not be different from that of other patients treated at _____.

If you (your child) are injured as a result of taking part in this research study, emergency care, hospitalization and outpatient care will be made available by the hospital. This will be billed to you as part of your medical expenses. No money has been set aside by the hospital as compensation for a research-related injury.

PRIVACY

We request that you permit _____ to use the clinical data included in your treatment records for reporting the results of this program. The results will be reported to the National Heart, Lung and Blood Institute, the EMMES Corporation (the Medical Coordinating Center), the Food and Drug Administration, and the scientific community. No mention of your (your child's) name or any identifying information will appear in any of these reports. Data will be collected at least until September 2004 and may continue indefinitely after that date.

Your (your child's) research and hospital records are confidential. Your (your child's) name or any other information which can identify you (your child) will not be used in study reports or publications. However, representatives from the Medical Coordinating Center, the National, Heart, Lung and Blood Institute, and the Food and Drug Administration or other authorized agencies may inspect your clinical records without removal of such identifying information.

CORD BLOOD TRANSPLANTATION STUDY EXPANDED ACCESS PROTOCOL

RIGHT TO REFUSE OR WITHDRAW

If you (your child) begin the study, you still have the right to withdraw at any time. Please submit in writing to _____ (*Name of IRB Contact Person*) of your (your child's) decision to withdraw from the study. If you (your child) should withdraw, you (your child) will be offered other available care which suits your (your child's) needs and medical condition. In either case, there will be no penalty or loss of benefits to which you (your child) are entitled.

If you decide to withdraw from this proposed treatment **before** receiving the high doses of drugs, we will continue to offer you (your child) the best available alternative care according to your (your child's) needs and physical condition. However, if you withdraw from this treatment plan **after** administration of TBI or high doses of chemotherapy, but before infusion of the umbilical cord blood cells, you (your child) might die. The reason is that you (your child) would be left without enough cells in the marrow to produce the white blood cells, platelets and red cells necessary to sustain you (your child).

INSTITUTIONAL REVIEW

_____ (*Name of IRB*) is legally responsible for making sure that research with study participants is appropriate and that the participant's rights and welfare are protected. It has reviewed and approved this study.

The physicians in charge of this study are _____ (*Names of Physicians*). If you need more information about this study before you decide to join, or at any other time, you may wish to contact one of them. If you have a question you may call for information about the consent process, research patient's rights, or research-related injury is _____ (*Name of IRB Contact Person*) at _____ (*Phone Number*).

