**Name of Cord Blood Bank**

**Protocol Title**

## INVITATION AND PURPOSE

You are invited to donate your baby’s cord blood for medical research. You are being invited because you have already agreed to donate your baby’s cord blood to <*name of cord blood bank*> for patients in need of a transplant. There are many reasons that cord blood may not meet the requirements for transplant. Cord blood not meeting these requirements can be used for medical research.

<*name of cord blood bank*> gives investigators cord blood units to use in medical research. Although the exact studies for which cord blood units may be used is not known at this time, the following are types of studies in which these units may be included.

Studies to: <*list types of studies outlined in the protocol*>

<*include following paragraph if it is in agreement with what is in the protocol*>

In addition, researchers may conduct research studies with cord blood units that have had all identifiers removed.   In these studies, there will be no way for the unit to be linked to you.  <*name of cord blood bank*> may allow researchers to use these anonymous cord blood units for many other kinds of studies.  These studies are not limited to the types of studies listed above, or related to transplantation in general.

### PROCEDURES

If you agree to donate your baby’s cord blood unit for medical research, nothing additional is required from you. After the cord blood is collected it will be tested to see if it meets all the requirements for transplant. If it does not meet the requirements for transplant, the cord blood may be used for medical research.

Your baby’s cord blood will be frozen and stored indefinitely for possible use in future research studies. <*Include the following if is in agreement with what is in the protocol*> Cells from the cord blood may be grown in the lab so there are more of them that can be used in research studies. DNA, the genetic portion of the cells, may be used in some of the studies.

All research studies using cord blood must first be approved <*briefly describe the approval process at the cord blood bank for approving these studies*>

1. *POSSIBLE Risks and Benefits*

There are no physical risks to your or baby by donating the cord blood to be used in medical research. The decision to use the cord blood for medical research is only made after the cord blood is collected and it does not meet the requirements for transplant.

There is a small risk that an unauthorized person could find out which cord blood unit is your baby’s. <*name of cord blood bank*> has procedures in place to keep your

data private. No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings.

You or your baby will not be helped by donating your baby’s cord blood for medical research. However, this research may help future patients who need a transplant.

### Confidentiality

<*name of cord blood bank*> will not intentionally tell anyone that you donated your baby’s cord blood for medical research. <*name of cord blood bank*> will try hard to make sure no one outside the <*name of cord blood bank*> will know which cord blood unit is yours.

### REIMBURSEMENT AND COSTS

You will not be paid for donating your baby’s cord blood for medical research. It will not cost you anything to donate your baby’s cord blood for medical research.

### VOLUNTARY PARTICIPATION IN AND WITHDRAWAL

It is up to you if you want to donate your baby’s cord blood for medical research. If you choose not to, <*state here if the cord blood unit will be destroyed if it does not meet the requirements for transplant*>.

If you decide to donate your baby’s cord blood for medical research you may change your mind at any time in the future. If you decide you don’t want your baby’s cord blood used for medical research, your baby’s cord blood will be destroyed. This will not affect your relationship with <*name of cord blood bank*>. <*insert who to contact to withdraw*>

#### Alternative to Participation

You may choose not to donate your baby’s cord blood for medical research. If you choose not to <*describe what will happen to the unit, be listed for transplant, destroyed, etc.*> .

### VIII. QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints about donating your baby’s cord blood for medical research contact *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Medical Director)* at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*(Coordinator)* at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

If you have questions or concerns about your rights as a research subject or about potential risks and injuries, please contact <*insert name and contact information for IRB representative*>. You will be given a copy of this consent form for your records.

*IX. SUBJECT’S Statement of Consent*

I have read this consent form and I have been given the opportunity to ask questions.I voluntarily agree to donate my baby’s cord blood for medical research studies as defined in this consent form.

*Subject Signature Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Print Name of Subject*

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with donating my baby’s cord blood for research have been explained to the above individual and that any questions about this information have been answered.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Counseling Healthcare Professional Date*

**Use of an Interpreter:** Complete if the subject is not fluent in English and an interpreter was used to obtain consent.

Print name of interpreter: Date:

Signature of interpreter: Date:

An oral translation of this document was administered to the subject in   
(state language) by an individual proficient in English and   
(state language). See the attached short form addendum for documentation.