**Name of Cord Blood Bank**

**PROTOCOL TITLE**

Investigator name and address

Version Date

Version Number

# Background

## 1.1 Name of Cord Blood Bank

Provide a short description of the cord blood program. Include when it was established, the number of cord blood units currently in inventory, the estimated number added each year, how many were distributed for transplant and how many were distributed for research.

## 1.2 Purpose of the Cord Blood Unit (CBU) Research Inventory

List the types of studies for which the cord blood bank will allow the cord blood units to be distributed.

List any types of studies that would specifically be prohibited, if any.

# Eligibility to Participate in the CBU Research Inventory

## 2.1 Maternal Donors

Describe what criteria are used to determine if a cord blood unit will be included in the CBU Research Inventory. For example:

*Maternal donors are eligible to participate in the CBU Research Inventory if they have donated their baby’s cord blood to (insert name of cord blood bank) and provided IRB- approved informed consent to allow the cord blood unit to be distributed for research.*

## 4. Establishing CBU Research Inventory

State how cord blood units will be collected for research. Will the units in the research inventory only be those units that are collected for research but don’t meet the criteria for transplantation? Will units that meet the criteria for transplantation ever be distributed for research? If so, under what circumstances? Will any units ever be collected specifically for research with no intention to use the unit for transplantation? If so, under what circumstances?

# 5. Unit Storage and Processing

## 5.1 Storage

Provide a short description of how the units are stored (e.g., liquid nitrogen).

## 5.2 Processing

If the units will be transformed or expanded in any way at the cord blood bank prior to distribution to the researcher, describe in this section.

## 5.4 Cord Blood Unit Labeling

Describe how the units are labeled.

# 6. Duration of Unit Storage at the Cord Blood Bank

Describe how long the units will be retained and the circumstances, if any, under which the unit may be destroyed. Address what will happen to the inventory if the cord blood bank closes.

# 7. Access to Units for Research

## 7.1 Who May Request Access to Units

Describe who will have access to these units for research purposes.

## 7.2 How Requests Are Reviewed/Approved

Describe how researchers request units for research and who is responsible for reviewing and approving those requests.

# 8. Use of Cord Blood Units for Research Studies

Describe here what types of research will be allowed with units. For example, will linked research be allowed? Linked research is defined as any research where a mechanism exists to trace data or samples back to the identity of the research subject. Delinked or anonymous research is research where it is impossible under any circumstances to trace data or samples back to the identity of the research subject.

***8.1 Linked Research***

## If linked research is allowed describe the types of studies and circumstances under which linked research would be allowed. Describe how those units are linked and what mechanisms are in place to protect the identity of the unit.

## 8.2 Delinked (Anonymous) Research

Describe how samples will be labeled if the research is delinked or anonymous.

## 8.3 Studies Outside the Scope of this Protocol

Will studies ever be allowed that are outside the scope of this protocol? If so, what is the approval process for those studies? In this case the study will be subject to further IRB review and approval, including a determination of the requirements for additional informed consent, if any.

## 8.4 Data Available With Units

Describe what data, if any, will be released with the units.

##  Restrictions and Requirements on Unit Usage at the Investigative Site

 Describe any restrictions or requirements that will be placed on the CBUs. For example:

* Will commercial use of the units be allowed or prohibited?
* Will third-party distribution of the units be allowed or prohibited?.
* After testing is complete, will the investigator be required to dispose of the units according to local and state biohazardous waste laws?
* Units must not be retained indefinitely.
* Requestor will not receive any identifying information with the units that could possibly be used to link the sample to the contributing individual.

# 9. Participant Withdrawal from the CBU Research Inventory

# Describe how participants may withdraw from the CBU Research inventory.

# 10. Confidentiality

## 10.1 Coded Unit Inventory and Links to Personal Identifiers

Describe how the privacy and confidentiality of the units will be maintained. Describe who has access to the links to the personal identifiers.

## 10.2 Reporting Requirements for CBU Research Requests

Describe any progress reports, etc. that will be required from the investigator, if any.