SAMPLE CONSENT FORM

INFORMED CONSENT - HUMAN SUBJECTS

Project Title: **Early vs: late cord clamping in very low birth weight infants**

This study involves:

A. The nature, duration and purpose of the study:

You have been admitted to Women & Infant's Hospital and may be at risk for delivering your baby prematurely. If your baby is born between 24 and 27 6/7 weeks gestation he/she will be admitted to the Special Care Nursery. The care for your baby may include monitoring and treatment when needed of breathing, low blood pressure, infection, bleeding into the spaces in the brain and anemia. These problems are more frequent in babies born prematurely.

Usually a baby's umbilical cord is clamped right after birth by the obstetrician. Immediate cord clamping may lead to average to low amounts of blood in my baby's system. This, along with the need for frequent blood sampling in the first few days to weeks can contribute to anemia and low blood pressure and the need for transfusions in the newborn period. Delaying cord clamping for a few seconds can give the baby more blood volume and may decrease the need for transfusions when the baby is in the nursery. Smaller studies have shown that the babies with delayed cord clamping have better lung functioning, more red blood cells, and higher blood pressures than do babies with early clamping.

The purpose of this study is to determine if delaying the clamping of the cord for 30-45 seconds at the time of birth will result in an increase in the hematocrit (number of red blood cells) by 10%. This will enable obstetricians to clamp the cord at an optimal time for the premature infant. The duration of the study will be for the first twelve hours after birth. However information on your baby's progress will be collected for the duration your baby is hospitalized. There is no additional cost for your baby to participate in this study.

B. The means by which it is to be conducted:

When your baby is born, he or she will be randomly assigned to one of two groups. If the baby is assigned to the first group, the baby's cord will be clamped immediately after birth. If the baby is assigned to the second group, the cord will be clamped 30 -45 seconds after birth. During this 35 -45 seconds your baby will be dried off with warm towels, kept warm on a special mattress and his/her oxygen saturation monitored and oxygen given to the baby if needed.

A hematocrit level requiring 0.2 ml of blood will be obtained between 2-and 4 hours of age. If a hematocrit has already been ordered for clinical care we will use this measurement. The infant's blood pressure will be recorded hourly for the first 12 hours of life. All other care your baby receives will be the standard care received in the Special Care Nursery.

C. The possible benefit or lack of benefit to myself and/or my child:

If it is determined that delayed cord clamping decreases the need for transfusions in the nursery and your baby is in the late clamping group, your baby may have benefited from this. If your baby is in the early clamped group the baby will have received the usual care given to babies at Women & Infant's hospital.

D. The risks, hazards, and discomforts of this study:

The risk of delayed cord clamping (after several minutes) may be polycythemia (increased red blood cells) or hyperbilirubinemia (jaundice or yellow coloring of the skin). However, there are no known risks with delayed cord clamping for 30 - 45 seconds.

E. The possible alternative procedure:

Routine care which includes early cord clamping.

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1. I have been given an explanation of this study, including any experimental procedures, and an offer was made to answer my questions.
2. Any statistical information from the study may be used for professional education or research purposes. In no instance will any names be used. Medical information may be discussed at personal conferences with the physician and me or my family.
3. Information concerning me will be kept confidential to the extent possible by law and will not be available to the general public. Information may have to be released when reasonable cause is shown under government regulations, required by law, proper judicial order or to an official agent of the Food and Drug Administration or to the Department of Health and Human Services.
4. I will be told of any changes in the risks or benefits of this project.
5. I do not have to participate in this study.
6. I am free to withdraw consent and stop taking part in the study at any time, and I will still receive the best care possible for myself and/or my child.
7. In the event that injury occurs as a result of this research, I am requested to notify the Principal Investigator at 444-5648. Should I be injured in a research project, treatment will be provided in Women and Infant's Hospital or, at the arrangement of Women and Infant's Hospital, at another appropriate health care institution at no cost to me beyond that which third party payers will cover. Further information in regard to this provision may be obtained from Barbara Riter, Research Administrator, whose telephone number is 453-7677.
8. If I have any questions about this study or what is happening, I may call William Oh, M.D at 444-5648 or Angelita Hensman, R.N.C at 274-1122 x 1730. If I have questions about my rights as a research subject, I may call Barbara J. Riter, Research Administrator, 453-7677 at Women & Infant's Hospital.

Signature: _____ Date: _____ Time: _____

Name: (please print) _____Witness: _____

If not for self, relationship to subject: _____

Hospital policy stipulates that the signed original consent form is to be incorporated into the subject's medical record: one copy of the signed original consent form is to be given to the subject; and one copy of the original consent form is to be retained in the researcher's files.

THIS INDIVIDUAL WAS ENROLLED THIS STUDYON _____ (date)
(Signature of principal investigator or designee)
_____