APPENDIX B: Consent Form

[DRAFT CONSENT FORM: Hydrocortisone and extubation study]

[insert institution]
Consent to Participate in Research

A Randomized Controlled Trial of the Effect of Hydrocortisone on Survival without Bronchopulmonary Dysplasia and on Neurodevelopmental Outcomes at 22 – 26 Months of Age in Intubated Infants <30 weeks Gestational Age

Introduction

You are being asked to participate in a research study that is being done by [**insert PI name**], who is the Principal Investigator and **his/her** associates, from the Department of Pediatrics. We are inviting you and your baby to participate in this research study because your baby was born at less than 30 weeks gestational age and is receiving mechanical ventilation at 2 – 4 weeks of age. These babies have a very high chance of developing bronchopulmonary dysplasia (BPD), a chronic lung disease of premature infants. Infants with BPD may need extra oxygen or other breathing support for a long time, and have a higher risk of problems with growth and development. Medicines called glucocorticoids (or steroids) can decrease lung inflammation and may decrease BPD, but artificial steroids, such as dexamethasone, also have adverse effects in babies. Hydrocortisone is identical to the body's own glucocorticoid, called cortisol, which reduces inflammation in the body.

The purpose of this research study is to find out whether giving hydrocortisone to babies who are on a breathing machine can help get them off this respiratory support and lower their risk of developing BPD. We will also evaluate their development when they are about 2 years old. We are planning to enroll XXX babies at the [**insert institution**] and a total of XXX babies will participate nationwide.

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. Information about this study is available on a public registry website (http://clinicaltrials.gov/ Identifier: NCT01353313). We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to have your baby participate in the study, the following things will happen:

1. Your baby will be "randomized" into one of the two study groups described below. Randomization means that the group is chosen by chance. It is like flipping a coin. The first group will be given hydrocortisone for 10 days either through intravenous (IV) tubing or through a feeding tube if your baby doesn't have an IV. The other group is a comparison group who will receive salt water.

2. If your baby's ventilator settings and oxygen needs come down low enough, the clinical care team taking care of your baby will take out the breathing tube (extubate your baby) and monitor his/her breathing and oxygen in the same way they do for babies who are not in the study.

3. A research team member will review certain parts of your baby's medical record and collect information about your baby's feeding, growth, other medications, and medical conditions. Some medical conditions do not resolve until after your child has been discharged to another hospital or home, so the research team member may also request information from your child's doctors after discharge. By signing this consent you are giving your permission for the research team to request and receive this information about your child's medical conditions. We may also call you at home to learn how your infant is doing.

4. At 22 – 26 months after your baby's full term due date, your child will be evaluated by developmental specialists. During the testing the children are observed playing with toys and moving around the room. You will also be asked questions about your child's health since discharge home. This testing is routine for high risk babies and will be done at no cost to you. By signing this consent you are giving us your permission to collect the results of these evaluations. You and your child's doctor will be given the results of these tests and they will be explained to you.

How long will I be in this study?

If you agree to take part in this study, your baby will receive study medication for 10 days, and we will collect information while your baby is in the hospital and at 22 – 26 months after your baby's full term due date.

What are the risks or side effects of being in this study?

- High doses of steroids may cause an increase in blood sugar or blood pressure. We do not expect this to happen with this dose of hydrocortisone, but your baby's blood pressure and blood sugar will be monitored, and the study drug may be stopped if either the blood sugar or the blood pressure becomes too high.

- High doses of steroids given for more than 10 days may interfere with the body's ability to produce its own cortisol for a short time. We will monitor your baby for any signs of this problem and if it develops your baby can receive hydrocortisone and we will decrease it more slowly.

- During the first two weeks of life, some very premature babies develop a hole in their intestines (about 2 – 4%). Infants treated with **both** hydrocortisone **and** another drug called indomethacin at the same time have a higher risk for this problem. We are waiting until at least two weeks of age before giving hydrocortisone, and we will not put a baby into the study who got indomethacin in the two days before the study. If your baby develops a patent ductus arteriosus (PDA) that your doctor decides must be treated with indomethacin during this study, the study drug may be stopped.

- Hydrocortisone treatment of premature babies has not been linked to any later problems with growth or development. However, we will evaluate your baby's growth and development at 22 – 26 months after his/her full term due date, to check for any problems.

- There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study. Every effort will be made to keep your baby's medical record strictly confidential. There will be no patient identification in any study report that may be published later on.

- There could be other side effects that are not known at this time. For more information about risks and side effects, ask your study doctor.

What are the benefits to being in this study?

There may be no benefit to your baby from participating in this study. There may be a benefit to your baby if it turns out that hydrocortisone really is beneficial and your child is in the group that receives hydrocortisone. It is hoped that information gained from this study will help in the treatment of future babies born prematurely.

What other choices do I have if I do not want to be in this study?

The alternative is for your baby to not participate in this study. Your choice will not affect other medical care that your baby receives.

How will my information be kept confidential?

We will take measures to protect your privacy and the security of all your personal information. However, the law may require that research information be shared with the following:

- Federal government regulatory agencies;
- The National Institutes of Health Neonatal Research Network
- Research Triangle Institute (the organization that will analyze the data)
- The [**Insert institutional IRB name**]

- Your name will not be used in any published reports about this study. A copy of this consent form will be placed in your medical record.

Information contained in your study records is identified with a code rather than your baby's name. This coded information will be shared with the sponsor of the study by means of a computer. The list which links your baby's name to the code will be kept in the locked [**local institutional location**].

What are the costs of taking part in this study?

There is no charge to you or your baby for participating in this research.

What will happen if I am injured or become sick because I took part in this study?

[The following language is specifically required by UNMHSC. It may be changed or omitted as required by local institution]
If your baby is injured or becomes sick as a result of this study, [institution name] will provide your baby with emergency treatment. No commitment is made by the [**institution name**] to provide free medical care or money for injuries to participants in this study.

In the event that your baby has an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell your study doctor immediately if your baby has been injured or becomes sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the [**insert institutional information**] for more information.

Will my baby be paid for taking part in this study?

There is no payment to you or your baby for participating in this study. [**insert institutional wording for payment or travel expenses for follow-up**].

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

If you should decide to withdraw your child from the study during the study drug administration period, for reasons of safety, your child will have the study drug gradually decreased until off.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, [**principal investigator**], or **his/her** associates will be glad to answer them at [phone number], Monday through Friday 8:00-5:00 pm. If you need to contact someone after business hours or on weekends, please call[insert appropriate information]. If you would like to speak with someone other than the research team, you may call [insert information].

Whom can I call with questions about my baby's rights as a research subject?

If you have questions regarding your baby's rights as a research subject, you may call the [**insert information**]. The IRB is a group of people from **[institution**] and the community who provide independent oversight of safety and ethical issues related to research involving human subjects. For more information, you may also access the IRB website at [**insert information**].

CONSENT

You are making a decision whether to have your baby participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your or your baby's legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to let my baby participate in this study. A copy of this consent form will be provided to you.

_____
Name of Subject (print)

_____ _____/_____
Name of Parent/Legal Guardian (print) Signature of Parent/Legal Guardian Date

INVESTIGATOR SIGNATURE
I have explained the research to the subject or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____
Name of Investigator/ Research Team Member (print)

_____ _____
(Signature of Investigator/ Research Team Member) Date