# Appendix B: Sample Consent Form

## Informed Consent Form

Project Title: LATE HYPOTHERMIA STUDY FOR HIE

**Section a: the nature, duration and purpose of study:-**

My baby has been evaluated and diagnosed with hypoxic-ischemic encephalopathy (HIE). HIE results from decreased blood flow and oxygen to all organs in the body including the brain. In babies born near their due dates certain signs following sudden lack of oxygen have been characterized as HIE. Some of the causes include infections and problems with the placenta or the umbilical cord. The risk of death and the risk of handicaps in infants who survive moderate and severe HIE is 50%.

In this hospital infants with HIE diagnosed at less than six hours of age are cooled on a cooling blanket to decrease their body temperature to 33-34° C (91.4-93.2° F) for 72 hours. Mildly decreasing the baby's body temperature (induced hypothermia or body cooling) appears to be the most promising treatment available to protect babies brains based on studies of animals, adults and newborns to date. Safety studies done in neonates have shown no problems from cooling in babies in the first 72 hours of life.

Brain injury likely happens over days to weeks following HIE. It is unknown if body cooling is of benefit when started beyond 6 hours of age. It is also not known if a longer period of body cooling may be beneficial. The purpose of this research study is to evaluate whether body cooling begun between 6-24 hours of age and continued for 96 hours for infants with moderate to severe HIE will reduce death and improve outcomes at 18 months of age.

This study is sponsored by the National Institutes of Child Health and Development. The duration of study treatment is 108 hours (96 hours of cooling and 12 hours of rewarming) however information will be collected from the infant's entire hospital stay and all infants will be scheduled for tests of the nervous system, vision and hearing tests at 18 months of age in the Follow up Clinic at Women & Infant's Hospital. This testing is a very important part of this study.

**Section B: The means by which it is conducted:-**

My baby will be put into one of two groups:- 1) Induced hypothermia [body cooling] or 2) control [normal body temperature]. There is an equal chance that my baby will be assigned to either group. Infants in the body cooling group will be placed on a blanket designed to cool the baby. This blanket currently is in use in children's hospitals as a way to cool babies and children during surgery and is also used by many places to provide cooling for infants with HIE at less than 6 hours of age. My baby's temperature will be kept at or around 33.5° C (92.3° F) for 96 hours. Esophageal temperatures will be monitored by placing a narrow tube through the baby's mouth to just above the stomach. My infant's skin temperature will also be watched closely. At the end of the 96 hours my baby will be slowly rewarmed until a normal body temperature of 37°C (98.6°F) is reached. Body-cooling will be stopped if anything bad happens related to the

low temperature or if my baby needs ECMO (extra corporeal membrane oxygenation - the baby's blood bypasses his or her lungs and is oxygenated using the ECMO circuit).

If my baby is put by chance in the Control group he/she will be cared for as his or her clinical condition indicates. My baby will receive standard clinical care which will include monitoring of vital signs (including esophageal temperatures), blood pressure, breathing rate, and blood tests to make sure all my baby's organs are working properly. Esophageal temperature will be maintained around 37°C (98.6°F). Both skin and esophageal temperatures will be closely monitored and recorded until 108 hours of age.

Some babies with HIE may develop an elevated temperature. If this occurs treatment will be provided which may include tepid sponge baths or placing my baby on a cooling blanket to regulate and keep my baby's temperature within a normal range. My baby may be given medication to help him/her stay calm as part of his or her routine care if needed.

A visit will be scheduled for my baby with the Neonatal Follow up Clinic at Women & Infant's Hospital at 134 Thurber's Avenue (Suite 215) at 18 months of age. This visit will take approximately 1.5 to 2 hours. I will be reimbursed $25.00 for parking and transportation for this visit. There will be no added cost to me for my baby to participate in this research study.

**Section C: The possible benefit:-**

Body cooling may reduce brain injury and disability resulting from brain injury. If my baby is in the control group there will be no benefit from cooling, but there may be benefit from avoidance and treatment of hyperthermia if it occurs. Participating in the follow up part of this study will help with the early detection and treatment of any developing problems.

**Section D: The potential risks, and discomforts:-**

Body cooling may cause disturbances in heart rhythm, abnormal blood clot formation/bleeding and skin breakdown. These same problems can also occur without cooling because of lack of blood supply to all organ systems. My baby will be watched closely and treated for any side effects that may occur.

**Section E: Alternatives:-**

Standard clinical care with no body cooling.

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1. I have been told about this study. The experimental procedures have been discussed with me. I have had a chance to ask questions. My questions were answered to my satisfaction.
2. I authorize my confidential, protected health care information to be shared with individuals, persons and groups associated with this study. My confidential health care information will be used only as necessary to participate in this study. Except when required by law, I will not be identified in study records disclosed outside this Hospital by name, social security number, address, telephone number, or any other direct personal identifier. For records disclosed outside this Hospital the investigator or his staff will assign me a unique identifying code. The key to the code will be kept in a locked file in the Pediatric Research office.

   Information about the results of the study may be obtained after all enrolled patients have been seen for follow up and the data has been published by writing to Dr. Abbot Laptook at the following address:- Department of Pediatrics, Suite 1100, Women & Infant's Hospital, 101 Dudley Street, Providence, RI 02905.
3. I authorize as part of the study that Dr. Abbot Laptook and his study team report the results of study related laboratory tests (e.g.; blood counts, tests to measure liver and kidney function, respiratory status, diagnostic imaging tests such as ultrasounds, MRI's, CT scans and X-rays), placenta and or pathology reports to the Data Coordinating Center (Research triangle Institute). The results of my tests will also be shared with and used by the NICHD Neonatal Research Network.

   Information may have to be released when required by law when reasonable cause is shown under government regulations, or proper judicial orders. It may also be released to an official of the United States Food and Drug Administration, the United States Department of Health and Human Services, the United States Inspector General, the United States Office of Civil Rights, representatives of the NICHD, RTI and the Women & Infants Hospital and its Institutional Review Board. If my research record is reviewed by any of these groups, they may also need to review my entire medical record. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations.
4. I authorize the retention of the study results in my child's research record (until the child reaches the age of 21) At the end of this retention period, either the research information not already in the child's record will be destroyed or information identifying the child will be removed from such study results. Any research information in the child's record will be kept indefinitely.
5. Any information from the study will be used for education or research purposes. My child's or my name will not be used.
6. I will be told of any changes to the risks or benefits of this study.
7. I do not have to take part in this study.
   I do not have to authorize use of my confidential, protected health information. My authorization to share my protected, personal health information expires two years after the study and Follow up is completed and the results are published.
8. I am free to withdraw my consent at anytime. I am free to stop taking part in the study at any time. I will still receive the best care possible for me and/or my child. If I want to withdraw I should contact Dr. Abbot Laptook in writing and let him know I am withdrawing. His mailing address is Department of Pediatrics, Suite 1100, 101 Dudley Street, Providence, RI 02905. If I withdraw my consent or permission the information which has already been collected about me or my child by the Hospital or the researchers will be kept by the researchers or hospital. This information may be needed to complete reports of this research.

9. In the event that injury occurs as result of this research, I am requested to notify the Principal Investigator Dr. Abbot Laptook at 401-274-1122 extension 1221.

   Should I be injured in a research project, treatment will be provided at Women & Infants Hospital, or 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 may be obtained from Barbara Riter, Manager, Research Administration, whose telephone number is (401)-453-7677.

10. If I have questions about this study, I may call Dr. Abbot Laptook at 401-274-1122 extension 1221. If I have questions about my rights as a research subject, I may call Barbara Riter, Manager, Research Administration, at (401) 453-7677.
11. My permission to allow the investigator and research staff to review my child's and my personal health information will end after the study and Follow up is completed and the results are published
12. I will be given a copy of this signed consent form.

**Future contact:** I have initialed whether I authorize the researchers to contact me:

_____ I authorize the researchers to contact me in the future for research purposes.

Signature: _____ Date: _____ Time: ___:___ AM / PM

Name (please print):_____

Name of Translator (if used): _____ Translator's signature: _____

If not for self: relationship to patient: _____

Person who explained study: _____ Date: _____

Hospital policy states that the signed original consent form is to be included in the subject's medical record. One copy of the original signed consent form is to be given to the subject. One copy of the signed original consent form should be retained in the investigator's files.