# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE OF STUDY:** Home Phototherapy for Neonatal Jaundice: A Comparison Between the Little Sparrows Bili·Hut™ and the Medela Bilibed®, Assessing the Treatment Duration, Parental Satisfaction, Impact on Breastfeeding Duration and Exclusivity, and Health Care Costs.

I, _____, the parent/guardian of _____, have been asked to participate in a research study under the direction of Dr. Susanna Magee. Other professional persons who work with her as study staff may assist or act for her. All research projects carried out at Landmark Medical Center are covered by the rules of both the Federal Government and Saint Michael's Medical Center IRB.

The Information provided may contain words I do not understand. I will ask the study doctor or the research staff to explain any words or procedures that I do not understand.

## PURPOSE:

The purpose of this study is to compare the efficacy of at home treatment with the Little Sparrows Bili·Hut™ to the previously studied Medela Bilibed® in infants with neonatal jaundice (elevated bilirubin levels at birth). The study will also look at the success of outpatient treatment without readmission, breastfeeding duration and exclusivity, parental satisfaction, and the cost compared to neonates treated or readmitted to the hospital for neonatal jaundice

## DURATION:

Mine and my infant child's participation in this study will last for a period of one-year.

## PROCEDURES:

After signing this informed consent, your infant child will be randomized in a 1 to 1 ratio to receive treatment for the neonatal jaundice with the Little Sparrows Bili·Hut™ or Medela Bilibed®. Both devices are United States Food and Drug Administration approved for the treatment of neonatal jaundice. Your infant child will have blood drawn to determine bilirubin levels at Initiation of treatment, the following morning (no later than 24 hours after treatment begins), each subsequent morning until bilirubin has decline enough to stop treatment, and 8-24 hours after stopping the phototherapy, If the levels have risen and phototherapy needs to be restarted, another level will be drawn12-24 hours later. You will be contacted at 1, 3, 6, and 12-months post phototherapy treatment

Parent/Guardian Initials:

to answer survey questions from study staff. The study will also collect data associated with your healthcare cost while participating in this study. The only procedures not considered standard of care are: 1) bilirubin level at initiation of treatment and 2) answering survey questions.

**PARTICIPANTS:**

20 breast-feeding mothers and 20 infants will participate in this study.

**INCLUSION CRITERIA:**

1. Willingness to sign informed consent
2. Planning to breastfeed infant
3. Parents ≥18 year of Age
4. Infants born at ≥37 weeks gestational age who are ≥2500 grams at birth

**EXCLUSIONS:**

1. Infants placed in care of the state after birth

**RISKS/DISCOMFORTS:**

There is minimal risk from your participation in this study. There is the risk of pain and bruising form collection of a blood sample at initiation of treatment since it is not the standard of care. As with any study involving collection of data, there is a possibility of breach of confidential data. I have been advised that signing this informed consent does not change any legal right I may have.

**BENEFITS:**

I have been told that I will receive no direct benefit from my participation in this study, but the information obtained from this investigation may help set the standard of care for treating otherwise well infants with jaundice at home and help families experience all the benefits that come with this service.

Parent/Guardian Initials:

**ALTERNATIVES:**

The alternative is not to participate in this study. If your infant child has neonatal jaundice, they can be treated without having to participate in this study.

**NEW FINDINGS:**

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

**CONFIDENTIALITY:**

Every effort will be made to maintain the confidentiality of my infant's study records. Landmark Medical Center will be allowed to inspect sections of my infant's medical and research records related to this study. If the findings from the study are published, my infant will not be identified by name. My infant's identity will remain confidential unless disclosure is required by law.

**FINANCIAL COSTS TO THE PARTICIPANTS:**

This research will be of no costs for the participants. Only diagnostic tests that would ordinarily and routinely be ordered for elevated bilirubin levels will be ordered.

**PAYMENT FOR PARTICIPATION:**

I will not be paid for my participation in this study.

**RIGHT TO REFUSE OR WITHDRAW:**

I understand that my participation is voluntary, and I may refuse to participate, or may discontinue my participation at any time, without penalty or loss of benefits to which I am otherwise entitled. I also understand that the investigator has the right to withdraw me from the study at any time.

**INDIVIDUAL(S) TO CONTACT:**

If I have any questions about my treatment or the research procedures, I can contact:

Dr. Susanna Magee at (401) 439 9276

Parent/Guardian Initials:

If I have concerns only regarding my **rights as a research participant,** I may contact Constantinos Costeas, MD IRB Chairman, at (973) 877-5212

I will receive a copy of this consent form if I agree to participate in this research study.

Parent/Guardian Initials: _____

**SIGNATURE OF PARTICIPANT**

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Infant Participant Name: _____

Infant's Parent/Guardian Name: _____

Infant's Parent/Guardian Signature: _____

Date:_____

**SIGNATURE OF WITNESS**

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian), and I am a witness to the fact that the participant (or his/her parent or legal guardian) signed this document.

Witness Name: _____

Witness Signature: _____

Date: _____