

Informed Consent Statement for:

Cycled Phototherapy Study

Key Information

This page is a summary of the main ideas about this research study. Detailed information is on later pages.

Why Do this Study?

Jaundice (yellow skin with elevated bilirubin amounts) is common in premature babies. It is prevented or treated with phototherapy (special lights). These lights are usually left on all the time (**continuous phototherapy**) until the bilirubin decreases. This study will test whether using **cycled phototherapy** (with the lights on for only part of each per hour) will improve the survival of extremely premature babies and keep the bilirubin amounts in a safe range.

What will happen in the study?

Babies can be in this study if their doctor determines that they need phototherapy. Babies in this study will be put into one of two groups: one group will get **continuous phototherapy** (the way that phototherapy is usually given) and the other group will get **cycled phototherapy** (what is being studied).

What Are the Possible Main Risks?

Continuous Phototherapy:

- Too much light may cause injury or increase the risk of death.

Cycled Phototherapy:

- The amount of bilirubin in the body may be slightly higher, which may increase the chance of brain injury.

What Are the Possible Main Benefits?

Continuous Phototherapy:

- The amount of bilirubin in the body may be slightly lower than with cycled phototherapy.

Cycled Phototherapy:

- You may have more time to interact and make eye contact with your baby.
- Less light may lower the risk of death or injury to the body or brain.

What If I Decide Not To Have My Baby Be In The Study?

Your baby will receive <insert local standard care>.

Investigator

<Name>

Location

<Location>

Telephone

XXX-XXX-XXXX

Protocol Title

Cycled Phototherapy: A Safer Effective Method to Control the Serum Bilirubin of Extremely

Invitation to take part

We are asking you to allow your baby to be in a research study about the treatment of jaundice. Premature (born early) babies can be part of this study.

Before you decide whether or not to let your baby be in the study, you need more information. It is important for you to know why this research is being done and what it means for your baby to be part of this study. Please take time to read this information carefully. You may talk about this study with family, friends and others if you wish. If you have any questions, please ask us.

This study is sponsored by the *Eunice Kennedy Shriver NICHD (National Institute of Child Health and Human Development)*, which is part of the NIH (National Institutes of Health). It is being done at <name of site> by <name of PI>.

What treatments are used for jaundice?

Bilirubin (bil-i-ROO-bin) is made when red blood cells breakdown normally and can cause jaundice (yellow skin). Nearly all premature babies have jaundice in the first several days after birth. Very high bilirubin amounts can cause brain injury with learning, movement, and hearing problems, a condition called kernicterus. Phototherapy (light therapy) is used to reduce the bilirubin and treat the jaundice.

Why is this study being done?

Babies getting phototherapy usually have **continuous phototherapy** (lights on all the time). However, phototherapy light easily goes through the thin skin of premature babies. Too much light may damage the cells in the body, and could increase the risk of dying.

Elevated amounts of bilirubin can also be lowered by using **cycled phototherapy** (lights for only 15 minutes of each hour).

Doctors are not sure whether continuous or cycled phototherapy is the better way to treat elevated bilirubin.

What is the main purpose of this study?

This study will test whether using cycled phototherapy will increase the survival of extremely premature infants and keep bilirubin levels in a range that doctors feel is safe.

How many babies will be in this study?

About 1,700 babies in the United States will join this study. ## babies from <site> will be part of the study.

What will happen if my baby is in this research?

Your baby will be treated with phototherapy to prevent high bilirubin amounts. This usually happens a day or two after birth. Your baby's bilirubin will be measured each day for the first 7 days after birth, and, when needed, for the next 7 days.

If you agree for your baby to be in this study, he/she will be treated with phototherapy in one of two ways:

- 1) **Continuous phototherapy**, which your baby would get if he/she was not in this study. The phototherapy lights will be on continuously (60 minutes per hour) to keep bilirubin amounts in a range that doctors believe is safe. Your baby's eyes will be covered while the phototherapy lights are on.
- 2) **Cycled phototherapy**. The lights will be on for 15 minutes of each hour. If needed, we will increase the time to 30 minutes of each hour or to continuous (60 minutes of each hour) to keep bilirubin amounts in a range that doctors believe is safe. Your baby's eyes will need to be covered only when the phototherapy lights are on.

Which method your baby would receive would be based on chance, like a flip of a coin. He/she would have an equal chance of being assigned to either group.

Your baby will receive all other usual care while in the hospital. We will collect information about how your baby does during his/her hospital stay.

Follow-up

After your baby goes home from the hospital, we would like to see him/her at about 2 years old to test his/her learning, movement and development. This follow-up visit is not part of this study, but we will collect information from the visit and can help you to find help if your baby if he/she has problems that need treatment.

Sometimes, we can learn from seeing how children are doing at school age. We would also like to contact you if we plan more visits later on.

How long will my baby be in this study?

Your baby will be in this study until he/she leaves the hospital. While he/she is in the hospital, the continuous or cycled phototherapy will be used during the first 14 days. Phototherapy is usually not needed after 14 days. However, if it is needed, it will be given as your baby's doctor decides.

What are the possible risks and discomforts from being in this research study?

Continuous phototherapy

If your baby receives continuous phototherapy, the treatment and, therefore, the risks, will be the same as if he/she were not in the study. Receiving too much light from continuous phototherapy might cause injury or increase the chance of dying.

Cycled phototherapy

Cycled phototherapy may improve survival by reducing the amount of phototherapy used.

Version Date:

Because the lights are on less, bilirubin amounts may be a little higher than with continuous phototherapy. There is a small chance that this could increase in the risk of a brain injury that could cause learning, movement, and hearing problems. However, if your baby's bilirubin amounts start to get too high, the doctors will use phototherapy continuously and increase the power of the lights, if needed.

The risks due to prematurity, including a need for phototherapy, are similar in the two groups. In both groups, if the bilirubin amounts get very high, your baby's doctors may treat him/her by giving him/her an exchange transfusion of blood with lower bilirubin in it.

Unknown Risks

There may be risks to being in this study that are not known at this time. If we learn of any new risks while your baby is in this study, we will tell you about them.

Confidentiality

If your baby is in this study there is a small risk of loss of confidentiality or privacy. Every effort will be made to keep your baby's information confidential.

What are the benefits of being in this study?

Continuous phototherapy

If your baby is in the continuous phototherapy group, the benefits will be the same as if he/she received continuous phototherapy outside of the study. This includes slightly lower bilirubin amounts than with cycled phototherapy.

Cycled phototherapy

Your baby's eyes need to be covered only when the phototherapy lights are on. This may allow more time for eye contact and interaction with your baby. Cycled phototherapy may lower your baby's risk of death. It might also lower unknown risks of phototherapy.

Knowledge from this study may help future premature babies.

Will my baby's medical information be kept private/confidential?

Any personal information we collect about you or your baby will be kept confidential as required by law. A study number will be used to identify your baby. Only the study team will know your child's name.

We will do everything we can to keep your and your baby's records confidential. However, we cannot guarantee absolute confidentiality.

Your or your baby's personal information may be shared if required by law. Your and your baby's identity will not be shared in reports or publications about this study.

This research study has a confidentiality certificate that protects your baby's privacy. If a legal matter happens, researchers may not use anything that might identify your baby without your permission. The researcher may give information to authorities to prevent serious harm to you, your baby, or others.

You may give information to anyone you wish. If an insurer or employer learns that your baby is in a study and you agree to share study data with them, the researcher will do so. This means that you must also guard your baby's information.

Coded study information will be sent to the NICHD Neonatal Research Network's Data Coordinating Center, RTI (Research Triangle Institute) International, in Research Triangle Park, North Carolina. The University IRB (Institutional Review Board), FDA (Food and Drug Administration) and the OHRP (Office of Human Research Protections) may access these records.

Coded study information will be kept by <Local Research Institution> and RTI International and may be shared for future research in accordance with the NIH Data Sharing Policy. Information released

under this policy will not identify your baby or his/her participation in this research study.

A description of this study will be available on [ClinicalTrials.gov](https://clinicaltrials.gov), ID number NCT03927833, as required by U.S. Law. This website will not include information that can identify you or your baby. At most, the website will include a summary of the results of this study. You can search this website at any time.

<Insert Institution-specific HIPAA language, if applicable.>

What are the costs of being in this research study?

You do not need to pay to be part of this study. There will be no cost to you or your insurance, for any test, treatment or visit that is done only for this study. The other parts of your baby's care that would be billed to you or your insurance company as is usually done.

Will I be paid for being in this research study?

You will not be paid for your baby to be part of this study.

What happens if my baby is injured as a result of being in this research study?

<If relevant, insert institution-specific compensation for injury language.>

Is being in this study voluntary?

Yes, being in this study is voluntary. If you allow your baby to be in this study you are still free to withdraw him/her at any time. You do not have to give a reason for changing your mind.

If you do not let your baby join the study, he/she will get <describe local standard phototherapy>. He/she will receive all usual care that is available to him/her.

You may decide to not let your baby join or to withdraw your baby from this study later. Either decision will not affect the relationship you or your baby have with his/her doctor or other staff. Your decision will not change the care that your baby would normally receive.

<Describe any specific withdrawal procedures.>

New Information

Sometimes new information becomes available during a research study that might influence your decision to let your baby be in the study. If this happens, the study team will tell you about it and talk with you about whether you want your baby to stay in the study. If you decide to withdraw your baby at that time, the research doctor will make arrangements for your baby's ongoing medical care. If you decide to let your baby stay in the study, you may be asked to sign an updated consent form.

Right of Investigator to Withdraw Participants

The investigator can withdraw your baby from the study without your approval. One reason for withdrawal is new information that shows the risks of the study are greater than the benefits. Another reason is a severe problem that requires the study procedures to be stopped.

Who should I contact if I have questions or concerns about this study?

If you have any questions about the study or complaints or concerns during the study, you should contact the investigator (Dr. ____), the co-investigators (Drs. ____ or ____) or other study team members via the University Paging Operator: (xxx) xxx-xxxx, the University NICU (xxx-xxx-xxxx or the ____ NICU (xxx) xxx-xxxx, 24 hours a day. If you think your baby may have been injured from being in this study, you can contact the same people.

Institutional Review Board

Contact the IRB (Institutional Review Board) if you have questions regarding your baby's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the study team. The University IRB may be reached by phone at (xxx) xxx-xxxx or by e-mail at irb@xxxxx.edu.

We are always available to answer your questions. If you have any questions that come up during this study, please be sure to ask us

STATEMENT OF CONSENT

I confirm that I have read this parental Informed Consent document. I have been able to ask questions about it. I will be given a signed copy of this form to keep.

I agree to allow my baby to be in this research study <insert if HIPAA authorization is bundled: and authorize you to use and disclose health information about my baby for this study>, as you have explained in this document.

Baby's Name

1st Parent/Guardian's Name

1st Parent/Guardian's Signature

Date

Relationship to Baby for 1st Parent/Guardian

<Insert 2nd Parent/Guardian line if necessary.>

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date