

Childrens Hospital Los Angeles  
**CONSENT/PERMISSION FOR CHILD TO PARTICIPATE IN RESEARCH**

**Sleep Disturbances in Children with Optic Nerve Hypoplasia**

Subject's Name:		
CHLA#:		Birth Date: <span style="border-bottom: 1px solid black;"></span>

**• INTRODUCTION**

You and your child are asked to participate in a research study conducted by Mark Borchert, M.D. from the Division of Ophthalmology at Childrens Hospital Los Angeles and Scott Rivkees, M.D. from the Division of Endocrinology at Yale University. You have been asked to participate in this study because your child has been diagnosed with optic nerve hypoplasia (ONH) and is currently participating in Dr. Borchert's prospective study on ONH. It is anticipated that 30 children and their parents/guardians will participate in this study. Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

**• PURPOSE OF THE STUDY**

The purpose of this study is to evaluate sleep disturbances in children with optic nerve hypoplasia (ONH). Through Dr. Borchert's study of ONH, it has been noted that a number of children with ONH have abnormal sleep-wake cycles. It is unclear why they have abnormal sleep-wake cycles but it may be due to the endocrine (hormone) problems associated with ONH.

In this study we are trying to determine what proportion of children with ONH experience these sleep disturbances. We will also evaluate the relationship of sleep disturbances and endocrine problems.

Even if your child does not experience any sleep disturbances, they may still participate in this study. Both children with normal and abnormal sleep-wake cycles are being asked to participate in this study in order to determine the true prevalence of sleep disturbances in children with ONH.

**• PROCEDURES**

If you and your child volunteer to participate in this study, we would ask you and/or your child to do the following things:

- 1) You will complete a Pediatric Sleep Questionnaire to assess potentially disordered sleep. The questionnaire has 70 questions with a yes/no/don't know response format. The questionnaire surveys sleep-disordered breathing, daytime sleepiness, and general sleep patterns. It also collects demographic information, your child's medical and psychiatric

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history, information about your child's school performance, family information and family sleep history.

- 2) You will complete a medication log listing your child's sleep medications and all other medications, along with the dose and how often your child takes the medication.
- 3) To measure your child's daily activity cycle, we will continuously monitor activity patterns of all participants for four or six weeks using Actiwatches. The Actiwatch is a small monitoring unit the size of a small wristwatch and is worn on the wrist. To monitor lighting intensity, watches will also be used that record external light exposure.
- 4) Based on whether or not your child takes sleep medication, your child will be placed in one of two groups. If your child has been taking sleep medication (e.g. melatonin), your child will continue his or her sleep medication while wearing the Actiwatch for two weeks and then discontinue the sleep medication for another four weeks while wearing the Actiwatch. You will be called weekly during the study by one of the investigators to determine if your child is having adverse effects from withholding the sleep medication. If your child is not taking sleep medication, he or she will wear the Actiwatch continuously for four weeks and you will not receive weekly phone calls.
- 5) Your child will be given an Actiwatch to wear for the four- or six-week period. He or she can engage in regular activities at home during the period of time he or she is wearing the Actiwatch. He or she should not wear the Actiwatch while swimming or bathing.
- 6) You will be given a stamped package to return the Actiwatch at the end of the monitoring period.

Based on the findings of this study, there may be a future research study for which you and your child may be eligible. There is a checkbox at the end of the consent form, for you to indicate whether or not you wish to be contacted for the future study.

• **POTENTIAL RISKS AND DISCOMFORTS**

The use of Actiwatches has not been associated with any problems and is similar to wearing a wristwatch. Your child should not experience any discomfort.

If your child is taking sleeping medications and the medication has been successful, your child may return to an irregular sleep schedule when the medication is discontinued during the study. The risk of stopping sleep medication is unknown. Your child may experience disrupted sleep, behavioral problems, or self-abuse behaviors. These problems may inconvenience and cause emotional stress to your child and your entire family.

Answering some of the questions in the questionnaire may make you feel uncomfortable or embarrassed.

There is a risk of accidental release of confidential information.

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There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

- **ANTICIPATED BENEFITS TO SUBJECTS**

There is no direct benefit to your child from participating in this study. You have the right to refuse permission for your child to participate in this study.

- **ANTICIPATED BENEFITS TO SOCIETY**

In the future, children with optic nerve hypoplasia (ONH) may benefit from this study if we are able to identify which children develop rest activity cycle disturbances. Eventually we may be able to normalize daily activity cycles with drugs, which will be of considerable benefit to the families with a child with abnormal sleep-wake patterns.

- **ALTERNATIVES TO PARTICIPATION**

The alternative is not to participate in this study.

- **FINANCIAL OBLIGATION**

Participants and their families are not responsible for any of the medical costs involved in this study. Neither you nor your insurance company will be billed for your participation in this research.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

Childrens Hospital Los Angeles and the physician investigators each maintain professional liability insurance to compensate patients for injuries caused by the fault of Hospital employees or physicians. The physicians are not employees or agents of the Hospital and are separately insured. If an injury is not caused by the fault of a Hospital employee or a physician, neither the Hospital nor the physicians provide reimbursement for treatment expenses or other compensation for the injury, and payment for care of such injury will be billed to you and/or your health benefit plan. You are not waiving any legal claims, rights or remedies because of your child's participation in this research study.

- **PRIVACY AND CONFIDENTIALITY**

Members of the research team and, if appropriate, your physicians and nurses will know that your child is a research subject. All results will be kept confidential, but may be made available to you, and/or your child's physician if you wish. Authorized representatives of the Department of Health and Human Services and the CHLA Committee on Clinical Investigations may need to review records of individual subjects. As a result, they may see your name and your child's name; but they are bound by rules of confidentiality not to reveal your identity to others.

No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

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- if necessary to protect your child's rights or welfare (for example, if he/she is injured and need emergency care); or
- if required by law (i.e., child abuse, reports of certain infectious diseases).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity.

Information gathered about your child through this study will be assigned the same code used in the other study your child is participating in, and his or her name will be removed. Data will be stored in a locked location and will only be accessible by those mentioned above.

Because this research involves the study of a medical condition, a copy of this consent form will be placed in your child's medical record. This will allow the doctors that are caring for your child to obtain information about what procedures your child is receiving in the study and treat him/her appropriately.

- **PARTICIPATION AND WITHDRAWAL**

Your child's participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no affect on your child's care, services or benefits at Childrens Hospital Los Angeles. If you agree to participate, but later decide to remove your child from the study, you may do so without affecting you or your child's rights to health care, services or other benefits at Childrens Hospital Los Angeles.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw your child from participating in this research if necessary to protect your child's health or if other situations arise that make it necessary to do so. If your child becomes ill during the research, he/she may have to drop out, even if he/she would like to continue. The investigator, Dr. Mark Borchert, will make the decision and let you know if it is not possible for your child to continue. The decision may be made either to protect your child's health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if your child experiences side effects, please immediately contact one of the investigators listed below.

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Mark Borchert at 323.361.4510. You may also contact Cassandra Fink, M.P.H. for any questions relating to your child's participation in this study. She may be reached at 323.361.2267, Monday through Friday, 8:00 A.M. through 4:30 P.M.

Evenings, nights, weekends or holidays you may call the hospital number, 323/361-2450 and ask for the Division of Ophthalmology Service doctor on-call.

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If your questions are not an emergency, you can obtain better information by calling Dr. Mark Borchert, Monday through Friday, 8:00 a.m. through 4:30 p.m., than by calling the Division of Ophthalmology on call service after hours.

• **FINANCIAL INTEREST OF THE INVESTIGATOR**

If your physician is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your doctor.

• **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your permission for your child’s participation at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as research subjects, you may contact the CHLA Office for Human Subjects Protections at 323/669-2265.

**SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE**

Your signature(s) below indicate

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your child’s participation in this research study; and
- You will be given a copy of the signed permission form and of the *Experimental Subject’s Bill of Rights*.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Name(s) of Parent(s)/Guardian

\_\_\_\_\_

\_\_\_\_\_  
Signature of Parent (Guardian)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent (Guardian)

\_\_\_\_\_  
Date

Please check one of the boxes below:

- I wish to be contacted for a future research study.
- I do not wish to be contacted for a future research study.

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**SIGNATURE OF INVESTIGATOR**

I have explained the research to the subject's parent(s)/guardian and answered all of his/her questions. I believe that he/she understands the information described in this document and freely gives permission for his/her child to participate.

\_\_\_\_\_  
Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date (must be the same date as subject's)

*Please check appropriate box and sign below.*

Investigator's Statement of Certification for Subjects less than Seven Years of Age (Assent)

The undersigned investigator, [Name], hereby certifies that he/she has discussed the information contained in the study consent to the subject, including any risks that may reasonably be expected to occur. The undersigned further certifies that the subject was encouraged to ask questions, that all questions were answered, and that assent was obtained.

Assent was not obtained for a subject under 18 years of age. *(Please state the reason. Examples include: child is an infant; child is comatose; child lacks cognitive abilities to understand the information.)*

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Time:

\_\_\_\_\_  
Signature

Routing of signed copies of the consent form:

- 1) Give to parent
- 2) Place in the CHLA Medical Record
- 3) Place in the Principal Investigator's research file.

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