

APPROVED

The SHIP Study
(Sleep Health in Preschoolers)
 Parental Permission and Consent Form

The Research Team:

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1. Researchers' Statement:

You and your child have the option to take part in a research study. The goals of this form are to give you information about what will happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions, or highlight any part of this form.

This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you and your child would like to take part in this research study, you will sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

2. What you should know about this study:

- This form explains what will happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you and your child choose not to be in the study, it will not affect your care at Seattle Children's or other institutions.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You will not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing the Sleep Health in Preschoolers (SHIP) research study to answer three questions:

1. Do families of preschool-age children with sleep problems benefit from extra help, or will the child's sleep improve anyway without extra effort?
2. Is the SHIP program an effective way to help improve child sleep?
3. What impact do early childhood sleep problems have on later development?

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you have a child who is 2 ½ to 5 years old who struggles with behavioral sleep problems that are not caused by a known physiological sleep problem.

5. How many people will take part in the study?

We think that about 500 families will take part in this research study.

6. If I agree to join this study, what will I need to do?

If you join the study, you and your child will complete assessments to help us understand your child's health and development, and work with your SHIP Case Manager to help improve your child's health and development. This study will last for 3 years, and there are 4 phases of the study over that time.

If you and your child join this study, you will be randomly placed in one of two groups. The group you are placed in will be decided by chance, like "flipping a coin" and you will not know your group assignment. The two study groups will be given different sets of materials on topics including, but not limited to childhood sleep health, tooth brushing and flossing, proper car seat use, bicycle and helmet safety, and reducing exposure to pesticides. We want to study the differences between the two groups.

The four phases of the study are as follows:

PHASE 1: Baseline

- This phase will last for 2-4 weeks.
- An Interviewer from the study team will visit your home once during this phase to conduct the consent conference, and to complete baseline measurements and assessments with you and your child. This visit will last for 1.5 - 2 hours.
- You will be asked to complete online surveys that will help us learn more about your child's sleep and development.
- Your child will be asked to wear an actigraph and you will be asked to complete a behavioral diary for your child (see below for more information).

PHASE 2: Active

- This phase will last for 3 months.
- At the beginning of this phase, a Case Manager will visit your home for 1-1.5 hours and will teach you strategies for promoting the healthy development of your child and help you problem solve how to use these strategies in your family's daily life.
- During this phase you will be asked to complete weekly phone calls with your Case Manager to talk about how things are going, to problem solve, and to set new goals for your child. The calls will be scheduled at a time that works well for you.
- You will receive parenting education materials via email or mail, including a monthly newsletter with information about things like health, safety, childhood sleep health, and environmental exposures.
- You will be asked to complete an online survey that will help us learn more about your child's sleep and development.
- At the end of this phase, your child will be asked to wear an actigraph and you will be asked to complete a behavioral diary for your child.

PHASE 3: Maintenance

- This phase will last for 9 months
- During this time you will be asked to complete monthly phone calls with your Case Manager to talk about how things are going, to problem solve, and to set new goals for your child.
- You will receive parenting education materials via email or mail, including a monthly newsletter with information about things like health, safety, childhood sleep health, and environmental exposures.
- Twice during this phase you will be asked to complete some surveys.
- At the end of this phase, your child will be asked to wear an actigraph and you will be asked to complete a behavioral diary for your child.
- At the end of this phase, an Interviewer will visit your home for 1.5 - 2 hours to take some measurements and complete assessments with you and your child.

PHASE 4: Follow-Up

- This phase will last for 2 years.
- An Interviewer will visit your home and take some measurements of you and your child once per year, for a total of 2 visits during this phase. These visits will last for 1.5-2 hours and will be scheduled at a time that works well for you.
- Your child will be asked to wear an actigraph twice during this phase, at which points you will be asked to complete a behavioral diary for your child.
- You will be asked to complete online surveys every 6 months for a total of 4 times during this phase.

- You will receive a monthly newsletter with information about things like health, safety, childhood sleep health, and environmental exposures.
- We will ask you to provide the name and contact information of your child's teacher. Your child's teacher will be asked to complete a survey about your child's behavior at school once per year for a total of 2 times during the Follow-Up phase.

Here is a visual diagram of the four phases and the study procedures:

	Phase 1: Baseline	Phase 2: Active			Phase 3: Maintenance				Phase 4: Follow-Up							
Month:	0	1	2	3	...	6	...	12	...	18	...	24	...	30	...	36
Home Visits- Interviewer or Case Manager	X	X						X				X				X
Measurements	X							X				X				X
Actigraph & diary	X			X				X				X				X
Parent surveys	X			X		X		X		X		X		X		X
Teacher survey												X				X

We will audio or video record portions of home visits and phone calls to make sure that assessments and interventions are being carried out consistently by all study staff and to assist with training. The digital audio or video files will be labeled without personal identifiers, stored in a secured location at our research facility, and will be deleted one year following the completion of the study, by 11/30/2019. It is also possible that a study supervisor may attend one of your home visits to observe the staff's (interviewer's or case manager's) consistency and to assist with training.

Explanation of Research Tests or Procedures:

If you and your child join the study, you will be asked to participate in several different types of assessments as mentioned above. These assessments will help us find out if being in this study causes any effects that are important to know about. We will use them to learn if an experimental strategy is helping or not, and to learn more about how child sleep affects development. An explanation of these assessments is provided below:

HOME VISITS:

An Interviewer will come to your home and:

- Explain the different assessment measures to you.
- Help your child do some fun activities, which seem like games and that also help measure learning and development.
- Complete some cognitive assessments with you and your child.

Your Case Manager will come to your home and:

- Teach you strategies for promoting the healthy development of your child.
- Help you problem solve how to use these strategies in your family's daily life.

MEASUREMENTS:

This type of assessment includes measuring the height, weight and waist of your child and yourself.

ACTIGRAPHY:

You child will be asked to wear an actigraph on his or her wrist for 7 days. An actigraph looks like a watch and measures your child's movement and sleep. A member of our research team will explain how to use the actigraph and answer any questions you have about it.

BEHAVIORAL DIARY:

You will be asked to record your child's sleep, media use, evening diet, illnesses, and medications for 7 days in a row. A member of our research team will provide instructions for the diary and explain everything that we would like you to keep track of.

PARENTAL SURVEYS:

The surveys will ask you questions about your child's sleep, behavior, and overall health, and about your experiences as a parent.

TEACHER SURVEY:

Your child's teacher or primary childcare provider (if your child is not yet in school) will be asked to complete a survey about your child's development and behavior.

7. How long will I be in the study?

If you choose to take part in this study, you will be in the study for about three years. Your information will be stored indefinitely.

If you and your child join the study, you can decide to stop **at anytime for any reason**. If you decide to stop, you will need to talk to your study Case Manager or other study staff.

The research study investigator could also decide to take you and your child out of this study. This might happen if you could not complete the home visits or assessments. If we ask you to leave the study, we will always explain why.

Banking or Storing Information

Storing information so researchers can use it in the future is called "banking". Researchers in this study may bank your information so they can share it with other researchers for future studies. When this happens, only non-identifiable information about you will be shared with researchers outside of our hospital.

8. What are the potential harms or risks if I join this study?

There are potential harms or risks if you take part in this study. Some are common and some are rare. These are described below.

Potential Harms and Discomforts:

- The primary risk of being a part of this study is the chance that the information you give us or recordings could be seen by other people that are not part of the study. However, there are many things that we do to make sure that your study information remains private. We will store all study materials and recordings in locked offices and on password-protected computers. If you decide to take part in the study, you will be given a Study ID number that will be used on all of your surveys instead of your name.
- The home visits could be stressful for you or your child. You might feel uneasy having the Case Manager in your home. You do not need to clean or do anything special to prepare for the home visits. You might feel uncomfortable answering some questions on the surveys. You could skip any questions you did not want to answer.
- You might feel frustrated during the phone calls with the Case Manager. During these calls, you are free to express your opinions and ideas. You can always decide not to use the suggestions the Case Manager makes.
- There is a risk of discomfort when your child wears the actigraph watch. You will be given specific instructions on how to use it, and many other studies have used actigraphs with preschool-aged children without complaints of discomfort. You can take the actigraph off during swimming.
- If we learn of information from you or your child that indicates potential risk or danger to your child (that is, possible physical or sexual abuse), we will take appropriate action to protect the safety of your child. This might include informing you of your child's status, providing you with referrals for services or counselors if needed, or contacting Child Protective Services if necessary.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

Being in this study might benefit you in the following ways:

- You will have access to helpful advice and receive free parent education materials.
- You may learn more about how to keep your child healthy and developing well.
- You will be able to talk to your Case Manager and problem-solve ways to make it easier to keep your child healthy and developing well.
- You may benefit from knowing that you are helping us understand the best way we can help other parents of preschoolers with trouble sleeping.

Potential Benefits for Others:

- We hope to use this study to help other parents learn how to develop healthy sleep habits in their young children.

10. What other options do I have?

If you choose not to be in this study, you can:

- Read books or articles about sleep in preschoolers.
- Talk to your pediatrician about your child's sleep, or make an appointment with the Sleep Disorders Clinic at Seattle Children's at Overlake.

11. How will you keep my information confidential?

If you take part in this study, we will make every effort to keep your information confidential.

We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file. If results of this research are published, we will not use information that identifies you.

We will only use your information for research. These are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.
- Sponsors, government agencies, or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential. Agencies or sponsors that may look at study records include:
 - National Institutes of Health (NIH)
 - Government Agencies
 - Others responsible for watching over the safety, effectiveness, and conduct of the research.

If you decide to take part in this study:

- We will store your information at Seattle Children's Research Institute. We will keep your consent form and contact information separately from the survey, research data, and audio/video recordings that will only be labeled with your Study ID number. Your information will be stored in a locked, secure facility or on a password-protected computer with access restricted to research team members.

- With the exception of audio and video recordings, we will store your information indefinitely. Stored information may include your contact information, surveys, assessments, diaries, actigraph information, interviews, and physical measurements. Audio and video recordings will be destroyed one year following the completion of the study, by 11/30/2019.
- After this study is over, we may share your information with members of this study's research team, with other researchers affiliated with Seattle Children's, or with researchers from educational or non-profit research institutions not affiliated with Seattle Children's.
 - If we do this, your information will be used for future research. We would do this if we received additional funding to study the long-term effects of child health on adolescent and adult health.
 - If we do this, we will go through an approval process with our Institutional Review Board to make sure that it is okay to do so. This is a group of scientists and community members who make sure research meet legal and ethical standards.
 - If we do this, we would not be able to share with you the results from that research. Further, your information could be used to make new products, tests, or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to pay you.
 - If we share your information with researchers outside of Seattle Children's, we will only share de-identified information and will not include your personal contact information.

You can always ask us to remove your personal information from our records. We would destroy any information that identifies you. However, we would not be able to destroy your de-identified information.

12. Will it cost me money to be in the study?

If you take part in this study, there will be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the study?

If you think you have been harmed from this study, please call the Principal Researcher Michelle Garrison at 206-884-8238.

14. Will I be paid if I join this study?

Yes. We will provide you with gift cards after completing different steps of this research study in order to thank you for your help.

At baseline, and months 3, 12, 24 and 36 of the study, you will be asked to complete surveys, a behavioral diary, and to have your child wear the actigraph watch for 7 days. At these time points, you will receive a \$30 gift card if you complete and return all study materials (survey, diary, and watch) within 14 days of the final day that your child wears the watch. If you are unable to return study materials on schedule, you may still receive a \$10 gift card for returning the surveys and the behavioral diary, and a \$10 gift card for returning the actigraph watch.

At months 6, 18 and 30 of the study, you will be asked to complete a survey. At these time points, you will receive a \$10 gift card for completing and returning each survey.

This means that if you complete and return all of your surveys, behavioral diaries, and actigraph watches on time during the study, you will receive a total of \$180 in gift cards.

In addition, if you submit an answer to a question that will be included in your monthly newsletter, you will be entered for a chance to win a prize with a value of approximately \$50. Every month, we will give away one prize to a randomly selected study participant who answers the newsletter question.

The IRS has certain rules about paying people who take part in research studies. If you take part in this study, we will ask you to provide your name and mailing address so we can pay you. The payments you will receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments of \$600 or more made to anyone in any year.

15. Who do I contact if I have problems, questions, or want more information?

 If I have questions or would like to know about ...	 You can call ...	 At ...
<ul style="list-style-type: none"> • Emergencies • Research-related injuries 	Michelle Garrison, PhD (Principal Researcher)	Phone: 206-884-8238
<ul style="list-style-type: none"> • General study questions • Any research concerns or complaints 	Heidi Gray, MS (Research Coordinator)	Phone: 206-884-1143
<ul style="list-style-type: none"> • Questions about your child's sleep or sleep plan 	Your Case Manager	Phone: 206-987-7447
<ul style="list-style-type: none"> • Your rights as a research participant 	Institutional Review Board This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: 206-987-7804

More Information:

A description of this research study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

16. If I join the study can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell the study staff. You can contact them by phone at 206-987-SHIP or email at SHIPStudy@seattlechildrens.org.

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

What if I changed my mind about banking my information?

If you ask us to stop banking your information, we would destroy all the information that identifies you. However, we would not be able to destroy or get data back if it has already been used by other researchers.

17. What will my signature on this form mean?

Your signature on this form will mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
 - You agree to take part in the research study.
 - You agree to have your child take part in this research study.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

Printed Name of the Child Participant

Printed Name of the Parent Participant

Signature of the Parent Participant

Date

Time

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

Printed Name of Researcher Obtaining Parental Permission or Consent

Signature of Researcher Obtaining Parental Permission or Consent

Date

Time

19. Future Research Studies

Would you like to know about future research studies? We would like to contact you in the future to tell you about other research studies you might want to take part in. Research is always a choice. We are only asking you if you would like to hear about other studies.

What happens if I check "YES"? If you check the "YES" box, you are allowing us to contact you if a study that you could take part in comes up. You can decide to stop allowing us to contact you at any time. You will need to call or email and let us know if you do not want to be contacted in the future.

What happens if I check "NO"? Deciding not to take part will NOT affect your care at Seattle Children's Hospital. There will be no penalty or loss of benefits to you for deciding that you do not want to be contacted in the future.

- Yes, it is okay for you to contact me about future research studies.
 No, please do not contact me about future research studies.

Please tell us what would be the best way to contact you.

- Phone: _____
 E-mail: _____
 Mailing Address: _____

Original form to:

Research Team File

Copies to:

Participant