Children's Hospital of Philadelphia

Informed Consent Form and HIPAA Authorization

Study Title: Implementing evidence-based behavioral sleep intervention in urban primary care: Aim 3

Version Date: June 9, 2021

Consent Name: Consent for Sleep Well! Aim 3

Principal Investigator: Ariel Williamson, PhD Telephone: (267) 425-1301

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Study Overview

You and your child are being asked to participate because your child is between the ages of 1 and 5 years, is a patient at a CHOP primary care clinic, and is having sleep problems.

The purpose of this research study is to find out whether Sleep Well!, a treatment program, can help with sleep problems in young children, and what parents think about the program. Sleep Well! can be implemented at your doctor's office, by telephone, or by video visit. It is usually 3 sessions with a Sleep Well! Therapist with some phone calls and text messages in between.

We want to know if the program is acceptable to parents. We also want to know whether child sleep problems get better after families participate in the program. If you participate, the study may last up to 6 months. You will fill out surveys about yourself and your child and you will be asked to use a device at home to measure your child's sleep.

We are interested in seeing how Sleep Well! compares to care you would usually receive at your doctor's office. Some caregivers will participate in the Sleep Well! intervention while another group of caregivers will be asked to follow-up with their doctor about getting help with their child's sleep.

The main risk of this study is a breach of confidentiality and potential embarrassment from the interviews and questionnaires. You will not benefit directly from participating in

this study, but you may learn how to help with your child's sleep. Risks and benefits of participating in this research study are described in detail below.

If you are interested in learning more about the study, please continue to read below.

How many people will take part?

About 120 families will take part in this study.

What is involved in the study?

If you participate in this study, you have a 50% chance of being placed in an enhanced usual care group. If you are placed in this group, you will still complete the baseline visit and the questionnaires, but then you will be given a handout with information about how to help with your child's sleep. You can also talk to your child's doctor about receiving other types of care for your child's sleep. The other half of participants will be placed in the Sleep Well! intervention group.

To help coordinate your care, the study team will be communicating with your child's pediatrician. This will include information about your enrollment in the study.

How long will you be in the study?

If you agree to take part, your participation may last up to 6 months. If you are assigned to the enhanced usual care group, you will have 3 visits. The first visit is a baseline assessment to fill out surveys. In the second visit, about 6 to 8 weeks later, you will be asked to fill out more surveys. About 6 to 8 weeks after that you will fill out surveys for a follow-up visit and participate in an interview that asks about your child's sleep.

If you are assigned to the Sleep Well! group, you will have a baseline visit to fill out surveys, 3 visits with your Sleep Well! Therapist during 6 to 8 weeks, and then a post-intervention visit about 1-2 weeks after you finish the Sleep Well! program. At the post-intervention visit, you will be asked to fill out surveys and participate in an interview that asks what you think about the Sleep Well! program. About 6 to 8 weeks after your post-intervention visit, you will have a follow-up visit in which you will be asked to fill out more surveys.

What are the study procedures?

The study involves the following procedures:

(A) VISIT 1: BASELINE ASSESSMENT
At the baseline visit, we will review your child's electronic medical record to collect information about your child's age, sex, medications that he or she is taking, services he or she has received, and other details.

You will be also be asked to complete questionnaires about you and your family, such as your age, sex, and relationship status, and about your child's sleep and behavior. You can complete these questionnaires either in person with a study team member, or on your own electronic device. If you choose to complete these questionnaires on your own device, we will send you a link to the questionnaires through your email, which you can use to enter your responses to the questions.

For 7 days after the baseline visit, you will be asked to complete a brief questionnaire to track your child's sleep on your own mobile device. We will send you a link to the questionnaires via text message, which you can use to enter your responses to the questions. If you do not wish to respond via text message, we will send a link to your e-mail to complete the daily surveys on your own electronic device.

You will also be asked to have your child wear an actigraph to monitor sleep. An actigraph is like a watch. Your child will need to wear it every day for 7 days around his or her wrist.

(B) VISITS 2-4: SLEEP WELL! INTERVENTION
If you are placed in the Sleep Well! intervention group, you will be scheduled to meet with a Sleep Well! provider for 3 sessions. Sessions can be completed at your doctor's office, by phone, or by video visit and will be up to 1 hour each. The intervention sessions will be audio-recorded so that we can review how the intervention was delivered. You will also be scheduled for 15-minute phone calls to check in with the Sleep Well! provider one week after each session. We will also send text messages about the intervention to your mobile device. You do not have to receive text messages if you do not want to. You will be involved in the Sleep Well! intervention for 6 to 8 weeks.

If you are in the enhanced usual care group, you will not have any contact with the study team during this time.

(C) VISIT 5: POST-INTERVENTION
You will meet with a study team member to receive an actigraph. You will be asked to have your child wear an actigraph to monitor sleep. An actigraph is like a watch. Your child will need to wear it every day for 7 days around his or her wrist.

During the 7 days that your child wears the actigraph, you will be asked to complete a brief questionnaire to track your child's sleep on your own mobile device. We will send you a link to the questionnaires through via text message, which you can use to enter your responses to the questions. If you do not wish to respond via text message, we will send a link to your e-mail to complete the daily surveys on your own electronic device.

After your child wears the watch for 7 days, you will be asked to complete questionnaires about you and about your child's sleep and behavior. You can complete the questionnaires either in person with a study team member, or on your own electronic device. If you choose to complete these questionnaires on your own device, we will send you a link to the questionnaires through your email, which you can use to enter your responses to the questions. We will also look at your child's medical record to monitor services he or she has received.

If you are in the Sleep Well! group, you will also be asked to complete an interview that is audio-recorded about your child's sleep about your thoughts on the Sleep Well! intervention. The interview can be done in person or over the phone. Some of your

answers will also be written down. No one other than the research team and the person who writes down the answers and the person who transcribes the interview will hear the recordings. If someone's name is mentioned, it will not be included on any notes made by the researchers.

(D) VISIT 6: FOLLOW-UP

You will meet with a study team member to receive an actigraph. You will be asked to have your child wear an actigraph to monitor sleep. An actigraph is like a watch. Your child will need to wear it every day for 7 days around his or her wrist.

During the 7 days that your child wears the actigraph, , you will be asked to complete a brief questionnaire to track your child's sleep on your own mobile device. We will send you a link to the questionnaires through via text message, which you can use to enter your responses to the questions. If you do not wish to respond via text message, we will send a link to your e-mail to complete the daily surveys on your own electronic device.

After your child wears the sleep watch for 7 days, you will be asked to complete questionnaires about you and about your child's sleep and behavior. We will also look at your child's medical record to monitor services he or she has received.

If you are in the enhanced usual care group, you will also be asked to complete an interview that is audio-recorded about your child's sleep. The interview can be done in person or over the phone. Some of your answers will also be written down. No one other than the research team and the person who writes down the answers and the person who transcribes the interview will hear the recordings. If someone's name is mentioned, it will not be included on any notes made by the researchers.

Visit Schedule

This table shows each study visit, what you will do (procedures) and how long it will last (duration).

Table 1: Sleep Well! Group

Visit	Main Procedures: What you will do	Duration: How long it takes
Baseline assessment (pre-intervention)	Medical record review Sleep diary by text message for 7 days Actigraphy (sleep watch) for 7 days Questionnaires about you and your child	8 days (10 minutes on day 1 for actigraphy instructions and start of usage, 5 minutes per day for the next 6 days, 40 minutes on 8 for survey completion)
Sleep Well! intervention	3 in-person intervention sessions Telephone calls about the intervention Text messages about the intervention	1 hour per session, 15 minutes per telephone call, over 6-8 weeks

	Questions about your child's sleep	
Post-intervention assessment (1-2 weeks after final Sleep Well! session)	Meet with study team member to receive an actigraph Actigraphy (sleep watch) for 7 days Sleep diary by text message for 7 days Medical record review Questionnaires about you, your child, and the intervention Interview about the intervention	8 days (5 minutes per day for 7 days, 60 minutes on day 8)
Follow-up visit (6-8 weeks after post-intervention)	Meet with study team members to receive an actigraph Actigraphy (sleep watch) for 7 days Sleep diary by text message for 7 days Medical record review Questionnaires about you and your child	8 days (5 minutes per day for 7 days, 40 minutes on day 8)

Table 2: Enhanced Usual Care Group

Visit	Main Procedures	Duration
Baseline assessment (pre-intervention)	Medical record review Sleep diary by text message for 7 days Actigraphy (sleep watch) for 7 days Questionnaires about you and your child	8 days (10 minutes on day 1 for actigraphy instructions and start of usage, 5 minutes per day for the next 6 days, 40 minutes on 8 for survey completion)
Post-intervention assessment (6-8 weeks after pre-intervention)	Meet with study team member to receive an actigraph Actigraphy (sleep watch) for 7 days Sleep diary by text message for 7 days Medical record review Questionnaires about you and your child	8 days (5 minutes per day for 7 days, 40 minutes on day 8)
Follow-up assessment (6-8 weeks after	Sleep diary by text message for 7 days Actigraphy (sleep watch) for 7 days Medical record review	8 days (5 minutes per day for 7 days, 60 minutes on day 8)

post-intervention)	Questionnaires about you and your child Interview about your child's sleep	

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following:

Risks related to Actigraph

There are no risks with wearing an Actigraph, which is the size and shape of a small wristwatch. Some participants may consider it a minor inconvenience. The study team will carefully clean and sanitize the actigraph before we give it to you and after you give it back to us. We can give you cleaning supplies for the actigraph if you want them.

Risks related to study parent/legal guardian surveys:

Some people might feel stressed or worried when answering questions about their family and their child's sleep problems. You do not have to answer any questions that make you too uncomfortable. Every family that participates in the study will also get a handout that lists mental health and safety resources for more support.

Risks associated with audio-recording and breach of privacy and confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. Some people may feel uncomfortable being audio-recorded. You may skip any question or stop the recording of the intervention session or individual interview at any time.

Every precaution will be taken to secure participants' personal information to ensure confidentiality. Each person who participates in this study will be assigned a study identification number. This number will be used to identify your data instead of names and other private information. We will keep a separate list that links each participant's name and medical record number to the study identification number for future reference and communication. We will destroy your audio-recorded intervention session files after they are no longer needed by the research team. We will convert your audio-recorded interview into a written transcript, and then destroy your audio recording. The audio recordings may be sent to an outside service for transcription. The audio files will be

sent via a secured connection and there will be no identifying information. Your interview transcript will be identified only by your study identification number.

Are there any benefits to taking part in this study?

You may benefit if the intervention or the enhanced usual care handout helps you to learn how to manage your child's sleep problems. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The information we get from this study may help doctors and behavioral health providers understand how to help young children with sleep problems.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please think about the study time commitments and responsibilities as a research subject when making your decision about participating in this study

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order for your child to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you or your child are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

There are options for you other than this study including not participating in this study. You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about your child will be collected. This will include information from your child's medical record, interview, and surveys. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Information about Sleep Well! treatment sessions will appear in your child's medical record, consistent with standards of clinical care. Other results from this study, such as surveys you complete and interview information, will not appear in your child's medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your or your child's identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The National Institutes of Health who is sponsoring this research;
- People from ACTS Document Management, the transcription company that may transcribe your interview data;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) issued by the National Institutes of Health covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information could be shared for:

- other scientific research;
- your medical treatment

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Ariel Williamson
Roberts Center for Pediatric Research, Room 8202
2716 South Street Blvd.
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

If you complete the surveys on your mobile device, standard data charges will apply.

Will you be paid for taking part in this study?

Yes, you will receive the following payment by ClinCard or cash. A ClinCard is similar to a Visa gift card. If you receive payment using the ClinCard, the bank will have access to your identifiable information. The bank will not have access to any medical information. Any cash reimbursement will comply with CHOP policy "Payments to Human Subjects."

- You will receive $25.00 for completing the baseline visit, $25.00 for completing the post-intervention visit, and $25.00 for completing the follow-up visit.
- You will receive $2.00 per day for each of the 7 days that you fill out the daily surveys about your child's sleep at pre-intervention, post-intervention, and follow-up. This means that you could receive $14.00 at baseline (pre-intervention) $14.00 at follow-up (post-intervention), and $14.00 at follow-up if you fill out these measures every day that you are asked to.
- You will receive $3.00 per day for each of the 7 days that you have your child wear the actigraph (sleep watch). This means that you could receive $21.00 at baseline (pre-intervention), $21.00 at post-intervention, and $21.00 at follow-up if your child wears the actigraph every day that you are asked to.
- You will receive an extra $10.00 for completing all of the daily diaries and actigraph procedures at each assessment period. This means that you could receive $10.00 at baseline (pre-intervention), $10.00 at post-intervention, and $10.00 at follow-up if you complete all of the daily diaries and actigraph procedures.

You can receive up to $210.00 if you complete this study.

Who is funding this research study?

The National Institutes of Health is providing funding for this research.

Please ask Dr. Ariel Williamson if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Ariel Williamson at 267-425-1301. You may also talk to your own doctor if you have questions or concerns. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes

sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Please indicate whether you would like to be contacted by other study teams at CHOP about participating in future research. This would not involve sharing your interview or video data from this study but rather our team may share your contact information so other teams can contact you about their studies.

_____ (initials) Other study teams **may not contact me** about participating in future research at CHOP
_____ (initials) Other study teams **may contact me** about participating in future research at CHOP

CONSENT TO TAKE PART IN THIS RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION FOR THE RESEARCH

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.
NOTE: *A foster parent is not legally authorized to consent for a foster child's participation. Caregivers agreeing to participate in this study must be the legal guardian for the child participant.*

Consent for Child's Participation

Name of Subject

Name of Authorized Representative

Relation to subject:
☐ Parent ☐ Legal Guardian

Signature of Authorized Representative

Date

Consent for Parent's/Legal Guardian's participation

Name of Parent/Legal Guardian

Signature of Parent/Legal Guardian

Date