



Informed Consent Form and HIPAA Authorization

Study Title: Implementing evidence-based behavioral sleep intervention in urban primary care: Aim 2

Version Date: October 22, 2019

Consent Name: Consent for Sleep Well! Aim 2

Principal Investigator: Ariel Williamson, PhD **Telephone:** (267) 702-0260

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 what parents think about Sleep Well!, a brief treatment program to help with sleep problems in young children. Sleep Well! is implemented at your doctor's office. It is usually 2-3 in-person sessions with some phone calls and text messages.

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 will last up to 12 weeks. You will fill out surveys about yourself and your child, participate in the Sleep Well! Intervention, and you may choose to use a device at home to measure your 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 manage your child's sleep. Risk 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 30 families will take part in this study.

What are the study procedures?

The study involves the following procedures.

(A) VISIT 1: BASELINE ASSESSMENT (PRE-INTERVENTION)

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, 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. 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 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.

If you are able to meet with the study team in-person, 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. The actigraph is optional, meaning you do not have to have your child do this if you do not want to.

(C) VISITS 2-3: SLEEP WELL! INTERVENTION

You will be scheduled to meet with a Sleep Well! provider for 2-3 sessions. Sessions will be at your doctor's office 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. 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 a 4-7 week period.

(D) VISIT 4: FOLLOW-UP

You will be also be asked to complete questionnaires about your child's sleep and about your thoughts on the Sleep Well! intervention. 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.

You will be asked to complete an interview about the Sleep Well! intervention. You will be asked what you think about the intervention and how it could be changed or improved. The interview will be audio-recorded. 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.

For 7 days after the follow-up 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 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.

If you are able to meet with the study team in-person, 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. The actigraph is optional, meaning you do not have to have your child do this if you do not want to.

Visit Schedule

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

Visit	Purpose	Main Procedures	Duration
Baseline assessment (pre-intervention)	Baseline surveys Daily diary *Optional: Actigraphy (sleep watch)	Medical record review Questionnaires about you and your child Sleep diary by text message for 7 days *Optional: actigraphy (sleep watch) for 7 days	8 days (40 minutes on day 1, 5 minutes per day for the next 7 days)
Sleep Well! intervention	Sleep Well! program evaluation	2-3 in-person intervention sessions Telephone calls about the intervention Text messages about the intervention	1 hour per session, 15 minutes per telephone call, over 4-7 weeks
Baseline assessment (pre-intervention)	Baseline surveys Daily diary	Questionnaires about your child and the intervention Interview about the intervention	8 days (60 minutes on day 1, 5 minutes

	<p>*Optional: Actigraphy (sleep watch)</p> <p>*Optional: actigraphy (sleep watch) for 7 days</p>	<p>Sleep diary by text message for 7 days</p> <p>*Optional: actigraphy (sleep watch) for 7 days</p>	per day for the next 7 days
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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.

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.

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 having the interview 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 interview 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 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
 The Children's Hospital of Philadelphia
 Sleep Center
 3401 Civic Center Blvd.
 Philadelphia, PA 19104

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 in cash or by ClinCard. 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.

- You will receive \$20.00 for filling out the baseline surveys.
- You will receive \$1.00 per day for each of the 7 days that you fill out the daily surveys about your child's sleep at baseline and follow-up. This means that you could receive \$7.00 at baseline (pre-intervention) and \$7.00 at follow-up (post-intervention) if you fill out these measures every day that you are asked to.
- You will receive \$2.00 per day for each of the 7 days that you have your child wear the actigraph (sleep watch). This means that you could receive \$14.00 at

baseline (pre-intervention) and \$14.00 at follow-up (post-intervention) if your child wears the actigraph every day that you are asked to.

- You will receive an extra \$5.00 for completing all of the daily diaries and/or actigraph procedures at baseline.
- You will receive an extra \$5.00 for completing all of the daily diaries and/or actigraph procedures at follow-up.
- You will receive \$30.00 for filling out the survey and completing the interview at follow-up.

You will receive up to \$74.00 if you complete this study but do not want to have your child wear the actigraph (sleep watch). You will receive up to \$102.00 if you complete this study and have your child wear the actigraph (sleep watch).

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 267-702-0260. You may also talk to your own doctor if you have questions or concerns.

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.

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.*

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