**Study Title:** Sleep Self-Management Intervention for Children With Juvenile Idiopathic Arthritis (SLEEPSMART)

**NCT Number:** NCT04066205

**Date:** March 23, 2020

## INSTRUCTIONS

- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example (**1.1**) must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

## INDEX



## 1 OVERVIEW

**Study Title:** **Sleep Shared-Management Intervention (SLEEPSMART) for 8-13 year old Children with Juvenile Idiopathic Arthritis (JIA)**

**1.1 Home institution**. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

*In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.*

*Note that many UW clinical faculty members are paid employees of non-UW institutions.*

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

UW School of Nursing, Department of Psychosocial and Community Health

**1.2 Consultation history**. Have you consulted with anyone at HSD about this study?

*It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.*

[ ] **No**
[x] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

Elizabeth Falsberg email 06/08/18

**1.3 Similar and/or related studies**. Are there any related IRB applications that provide context for the proposed activities?

*Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.*

*Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.*

[x] **No**
[ ] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

**1.4 Externally-imposed urgency or time deadlines**. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

*HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.*

*HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.*

☐ **No**

☒ **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

We have received a JIT from NIH/NINR who approved our DSMP, and now they are awaiting IRB approval before distributing the funds.

**1.5 Objectives** Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

This study is not more than minimal risk.
We aim to develop and test a technology-based sleep self-management intervention delivered for 8-to-13 year-old children with JIA and their parents. Initial feasibility, acceptability, and efficacy of the newly developed sleep self-management intervention will be tested in a pilot randomized controlled trial comparing the active intervention against standard care with a sample of 60 children with JIA and their parents.
**The specific aims are to**:

1. Develop a technology-based sleep self-management intervention (SLEEPSMART]) based on input and engagement from JIA children and their parents. We will use direct stakeholder input from 10 children and parents about their needs for sleep self- management as well as intervention material from our prior Web-based interventions for child with chronic pain to develop content for the SLEEPSMART. A beta version of the program will be evaluated by children, parents, and content experts.

2. Refine and enhance the intervention product during pilot deployment following user and family centered design principles. Test and refine the prototype of the intervention in two design iterations with 5 JIA parents and their parents. JIA children and parents will trial the prototype for 2 weeks. Focus groups and "think aloud" sessions will be conducted at each phase to identify refinement needs.

3. Assess the feasibility, usability, perceived usefulness, and initial efficacy of the resulting sleep self-management intervention (SLEEPSMART ) in a pilot RCT. The pilot RCT, comparing usual care to SLEEPSMART intervention, will mimic all of the major essentials of the future definitive trial to estimate effect size and to further refine. Primary outcomes: actigraphy sleep duration, sleep quality, and feasibility/acceptability. Secondary outcomes: child and parent self-management (activation, motivation, self-efficacy), technology use, recommendations and feasibility of innovative sleep monitoring.
- Aim 3 will involve 60 participants; 30 JIA children will be randomly (online generated program) selected to receive the online sleep intervention [active treatment group], and 30 JIA children will be in the control group.

Development of an effective technology-based sleep self-management intervention has the potential to improve health outcomes of children living with JIA. Findings regarding intervention feasibility and acceptability will guide future intervention optimization, and estimation of intervention efficacy will provide essential information for power calculations for the design of a future definitive trial of the intervention. The study will provide findings regarding the benefits of a potentially cost-effective intervention that could be implemented on a large scale to improve sleep health in children with chronic conditions and their parents. The Internet offers a unique opportunity to reach adolescents with JIA and provide the training in self-management strategies that otherwise may not occur due to treatment access and resource obstacles.

**1.6 Study design**. Provide a one-sentence description of the general study design and/or type of methodology.

*Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.*

Develop a technology-based sleep self-management intervention (SLEEPSMART) based on input and engagement from 15 JIA children and their parents, then describe the initial feasibility, acceptability, and efficacy of the newly developed sleep self-management intervention which will be tested in a pilot randomized controlled trial comparing the active intervention against standard care with a sample of 60 children with JIA and their parents.

**1.7 Intent**. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

*This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.*

| Descriptor |
|---|
| ☐ 1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research). |
| ☐ 2. Part of an institution, organization, or program's own internal operational monitoring. |
| ☐ 3. Improve the quality of service provided by a specific institution, organization, or program. |
| ☒ 4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that:<br>• Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or<br>• Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study. |
| ☐ 5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals. |
| ☐ 6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy. |
| ☐ 7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health. |

[x] 8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)

[ ] 9. Expanded access use of a drug or device not yet approved for this purpose

[ ] 10. Use of a Humanitarian Use Device

[ ] 11. Other. Explain:

**1.8 Background, experience, and preliminary work**. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

**a.** Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

*Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.*

There is a critical gap in the treatment of Juvenile Idiopathic Arthritis (JIA) wherein a majority of school-age children experience sleep deficiency, pain, and reduced health-related quality of life even with advances in medical management of the disease. Sleep deficiency, including inadequate quantity and poor quality, is a serious public health problem, is common and highly comorbid in JIA, with an estimated 20 to 25% diagnosed with insomnia during adolescence. Despite the pervasiveness of sleep deficiency in JIA, children receive no training in self-management strategies (activation, motivation, self-efficacy) that can help empower them to improve sleep quantity and quality before transitioning into adolescence. Lack of sleep self-management interventions in JIA represents an important problem because these children are more vulnerable to the long-term consequences of poor sleep, poorer health-related quality of life, and increased healthcare utilization. Further, studies in other chronic health conditions show that sleep deficiency is associated with lack of self-monitoring and goal setting - important components of self-management. Clinical resources to address sleep deficiency in JIA are not available, creating a significant unmet clinical need.

In considering the multiple needs of these children and parents, successful interventions will need to target self-management skills and be delivered to families in an accessible format. Based on the experiences of our team in developing and testing technology-based pain self-management interventions for children with chronic conditions and their families, and conducting usability studies for such tools, we hypothesize that this approach will also be effective for delivering a sleep self-management intervention for children with JIA and their parents. We aim to develop and test a technology-based sleep self-management intervention delivered for 8-to-13 year-old children with JIA and their parents. Initial feasibility, acceptability, and efficacy of the newly developed sleep self-management intervention will be tested in a pilot randomized controlled trial comparing the active intervention against standard care with a sample of 60 children with JIA and their parents. Sleep will

be measured using actigraphy, sleep diaries, & self-report measures. Problem-solving skills, motivation, beliefs about sleep, and sleep self-efficacy also will be measured before and after the intervention is applied.

**b.** Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

*It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.*

This proposal builds on my prior studies of sleep deficiency and symptoms in children with arthritis, and my existing collaborations with Drs. Palermo and Ringold, at Seattle Children's Hospital (SCH), as well as, Ching Hung, the clinical research associate in the Pediatric Rheumatology clinic who will assist with participant recruitment.

Strengths of this study: 1) prior successful recruitment of children with JIA using actigraphy and electronic sleep diaries; 2) expertise in sleep, JIA, actigraphy, symptoms, REDCap; 3) leveraging of successful methods in a prior studies; and 4) building on Dr. Ward's prior collaborations with pediatric rheumatology and pediatric psychology in child with chronic pain.

**1.9 Supplements**. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

*This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.*

| Check all That Apply | Type of Research | Supplement Name |
|---|---|---|
| ☐ | **Department of Defense**<br>The research involves Department of Defense funding, facilities, data, or personnel. | *ZIPLINE* SUPPLEMENT: Department of Defense |
| ☐ | **Department of Energy**<br>The research involves Department of Energy funding, facilities, data, or personnel. | *ZIPLINE* SUPPLEMENT: Department of Energy |
| ☐ | **Drug, biologic, botanical, supplement**<br>Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research | *ZIPLINE* SUPPLEMENT: Drugs |
| ☐ | **Emergency exception to informed consent**<br>Research that requires this special consent waiver for research involving more than minimal risk | *ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC) |
| ☐ | **Genomic data sharing**<br>Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers | *ZIPLINE* SUPPLEMENT: Genomic Data Sharing |
| | **Medical device** | |

| | | |
|---|---|---|
| ☐ | Procedures involve the use of <u>any</u> medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved | *ZIPLINE* SUPPLEMENT: Devices |
| ☐ | **Multi-site study**<br>(You are asking the UW IRB to review one or more sites in a multi-site study.) | *ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research |
| ☒ | **Participant results sharing**<br>Individual research results will be shared with subjects. | *ZIPLINE* SUPPLEMENT: Participant Results Sharing |
| ☐ | None of the above | |

## 2 PARTICIPANTS

**2.1 Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

**<u>Aim 1 & 2</u>**: Fifteen children, 9-11 years with JIA, and their parent will be recruited from the Rheumatology clinic at Seattle Children's Hospital (SCH). In Washington State, over 6,100 children have been diagnosed with JIA. Approximately 500 patients with JIA are seen each year in the Department of Rheumatology, and 250 are between 9 to 11 years.
**<u>Aim 3</u>**: Sixty children, 8-13 years, diagnosed with JIA and one parent will be recruited from the Pediatric Rheumatology Clinic at SCH and at The Children's Hospital of Philadelphia (CHOP), and remotely via flyers on social media.

Girls and boys are eligible, although we expect to enroll more Caucasian girls because of the heightened disease prevalence among Caucasian girls, and its relatively low prevalence in underrepresented minorities and boys.

**2.2 Inclusion and exclusion criteria.** Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

<u>Inclusion criterion for JIA children</u>: 1) diagnosed with JIA; 2) 8-13 years; 3) able to read/speak English; and 4) parent report that child has difficulties with sleep quality(difficulty falling asleep, no bedtime routine, waking up in the middle of the night and struggling to fall back asleep) and/or poor sleep impacts their child's day to day function (school, interacting with peers, hobbies).
<u>Exclusion criteria for JIA children</u> include: (a) diagnosed sleep disorder (obstructive sleep apnea [OSA]); 2) positive screen on the Pediatric Sleep Questionnaire (> 0.33) for OSA (we will suggest follow up with the child's primary care provider because treatment of this condition is beyond the scope this intervention); 3) lack of daily access to the Internet or mobile device as the study will be conducted online; 4) developmental delay; d 5) children who do not speak English; and 6) child is not currently participating in psychological therapy.

<u>Inclusion criteria for parents</u>: 1) > 18 years; 2) able to read/speak English; 3) access to a computer or web-based device to complete surveys.
<u>Exclusion criteria for parents</u>: 1) diagnosed with a chronic illness that would interfere with ability to complete study procedures; 2) lack of daily access to the Internet or mobile device.

For families in which the child routinely spends the night in more than one home, a primary study parent will be identified and asked to complete all assessments. Parent is defined as the adolescent's primary caregiver and who co-resides with the child more than 50% of the time.

**2.3 Prisoners**. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

**a.** Will you recruit or obtain data from individuals that you know to be prisoners?

*For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".*

[x] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

[ ] **Confirmed**

**b.** Is your research likely to have subjects who become prisoners while participating in your study?

*For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.*

[x] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

**2.4 Protected populations**. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

*The WORKSHEETS describe the criteria for approval but do not need to be completed or submitted.*

| Population | Worksheet |
|---|---|
| [x] Children | WORKSHEET: Children |
| [ ] Children who are wards | WORKSHEET: Children |
| [ ] Fetuses in utero | WORKSHEET: Pregnant Women |
| [ ] Neonates of uncertain viability | WORKSHEET: Neonates |
| [ ] Non-viable neonates | WORKSHEET: Neonates |
| [ ] Pregnant women | WORKSHEET: Pregnant Women |

*"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).*

**a.** If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

Study participants are child between 8 and 13 years of age, and their parent.

**2.5 Native Americans or non U.S. indigenous populations.** Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

*Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.*

*Examples: a reservation school or health clinic; recruiting during a tribal community gathering*

[x] **No**

[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

**2.6 Third party subjects.** Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

*"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.*

[x] **No**

[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

**2.7 Number of subjects.** Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

*Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:*

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

*Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:*

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

*The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.*

[ ] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

*Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.*

[x] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

| Group name/description | Maximum desired number of individuals (or other subject unit, such as families) who will complete the research<br>***For clinical trials: provide numbers for your site and for the study-wide total number*** |
|---|---|
| Children with JIA | 75 ([Aim 1[10] & Aim 2: 5 JIA children]; Aim 3: 60) |

| | |
|---|---|
| Parents of a child with JIA | 75 ([Aim 1 [10] & Aim 2: 5 JIA parents]; Aim 3: 60) |

## 3 RESEARCH SETTING

**3.1 Reason for sites**. Describe the reason(s) why you selected the sites where you will conduct the research.

We selected Seattle Children's and CHOP Pediatric Rheumatology clinics as our recruitment sites because the clinicians manage and care for children with JIA. We will also recruit JIA children outside of WA state via social media.

**3.2 Local context**. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

*Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.*

*This federal site maintains an international list of human research standards and requirements:*
*http://www.hhs.gov/ohrp/international/index.html*

In our prior research studies in which we recruited from Seattle Children's, we did not encounter cultural challenges with our measures or use culturally inappropriate procedures. We do not anticipate site- specific cultural issues, customs, or beliefs that would affect our research and how it is conducted.

**3.3 Site-specific laws**. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

**3.4 Site-specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect your research.

*Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.*

None

## 4 RECRUITING and SCREENING PARTICIPANTS

**4.1 Recruiting and Screening**. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

**Recruitment**
Recruitment will use several methods: SCH Rheumatology clinic; letters to JIA parents seen at SCH; posted recruitment flyers, social media posts.

**The below is broken down by Aims:**
Aims 1 & 2: will involve recruitment of 15 *JIA children and their parent* to do semi-structured interviews and test out the online modules.
**Recruitment**

Letters to JIA parents whose children are cared for at SCH, will be sent describing the study, and will include the clinical research associate's (CRA) contact information for questions.

**SCH**: JIA participants and their parents. The CRA will review the Rheumatology patient list for eligible child. A list of names and addresses for children who meet the above criteria will be obtained from the database and maintained by the CRA in a secure area. Potential subjects with JIA will be mailed a letter informing them about the study, and provide the CRAs contact information. During the clinic visit, the CRA will give eligible child and their parents the study flyer that includes information about the study at a clinic visit. (See Aims 1_2 Recruitment).

Aim 3: will involve 60 JIA children (8 to 13 years) and their parent, and the focus is on feasibility and acceptability of the online sleep (SLEEPSMART) intervention. 30 children will be randomized using an online program to the active treatment group (online sleep intervention- SLEEPSMART), and 30 will be in the control group.

The CRA will review the Rheumatology patient list for eligible child. A list of names and addresses for children who meet the above criteria will be obtained from the database and maintained by the CRA in a secure area. The CRA will contact potential subjects with JIA via the telephone to inform them about the study. Participants who are interested and/or unsure about the study, the CRA will email eligible child and their parents the study flyer that includes information about the study, and guide potential participants to https://www.sleepsmartstudy.org/ webpage, and will include the CRA contact information with questions..

Recruitment flyers will be posted in community-based pediatric primary care clinics, rheumatology clinics,recreational centers, and boys and girls clubs within and outside WA state.

Social Media posts will describe the study, and provide a link to the online screening webpage as well as the Clinical Research Associate (CRA) contact information. Posts may be made to UW School of Nursing

webpage/social media accounts, and Facebook. Posts will guide potential participants to https://www.sleepsmartstudy.org/ webpage.

**SCH**: JIA participants and their parents. The CRA will review the Rheumatology patient list for eligible child. A list of names and addresses for children who meet the above criteria will be obtained from the database and maintained by the research coordinator in a secure area. Potential subjects with JIA will be called informing them about the study that will guide potential participants to https://www.sleepsmartstudy.org/ webpage, and provide the CRAs contact information.

**CHOP**: Rheumatology staff at CHOP will review the Rheumatology database for eligible children. Staff at CHOP will mail eligible participants a letter informing them about the study that will guide potential participants to https://www.sleepsmartstudy.org/webpage. Interested participants will contact the CRA, who works at SCH, with questions.

**Screening:** The CRA at SCH will review the Rheumatology patient list for eligible youth. A list of names and addresses for children who meet the above criteria will be obtained from the database and maintained by the CRA in a secure area. Potential subjects with JIA will be called by the CRA who will inform them about the study. . Interested participants will contact the CRA with questions.

Aims 1& 2: Interested potential participants will contact the CRA by phone. For those who contact the CRA by phone, the CRA will screen potential participants initially over the phone (see Aims 1_2 Recruitment Script).

Aims 3: Interested potential participants may choose to visit https://www.sleepsmartstudy.org/webpagewebpage or contact the CRA by phone. For those who contact the CRA by phone, the CRA will screen potential participants initially over the phone (see Recruitment Script). For those who are eligible and interested, they will be directed to the https://www.sleepsmartstudy.org/webpage webpage (hosted by REDCap). From there, parents may complete the screening surveys including"does your child has difficulty with sleep quality and/or does poor sleep impact your child's day-to-day function (school, interacting with peers, hobbies)?" Sleep-Related Breathing Disorder Scale from the Pediatric Sleep Questionnaire (SRBD) and is your child currently receiving psychological therapy. Instruments are automatically scored within REDCap and indicates whether participants appear to meet eligibility criteria or not. Those who are not eligible are thanked for their time. Those that are eligible are advised that the study team will contact them (see recruitment follow-up script).

REDCap uses unique identifiers for potential participants and only the CRA and PI has the master list connecting potential participant email, names, and identifiers.

**4.2 Recruitment materials**.

**a.** What materials (if any) will you use to recruit and screen subjects?

*Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.*

Aim 1 & 2: Study flyer, letters to participants, Child Sleep Habits Questionnaire (CSHQ), Sleep-Related Breathing Disorder Scale from the Pediatric Sleep Questionnaire (SRBD) will be used to recruit and screen subjects.

Aim 3: Study flyer, letters to participants, social media posts, https://www.sleepsmartstudy.org/webpage , phone scripts, "does your child has difficulty with sleep quality and/or does poor sleep impact your child's day to day function?" Sleep-Related Breathing Disorder Scale from the Pediatric Sleep Questionnaire (SRBD), and parent report if the child is currently receiving psychological therapy will be used to recruit and screen subjects.

**b.** Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

*HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:*

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

**4.3 Relationship with participant population**. Do any members of the study team have an existing relationship with the study population(s)?

*Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).*

☐ **No**
☒ **Yes** → If yes, describe the nature of the relationship.

Pediatric Rheumatologists are the clinical care providers for child with JIA

**4.4 Payment to participants**. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

*The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.*

*Do not include a description of any expenses that will be reimbursed.*

Aim 1 & 2: Participants will receive a $25 gift card for each interview (2-3 interviews are anticipated), and $40 gift care to test the online module. Total estimated to be $90 - $115 depending if 2 or 3 interviews are needed.

Aim 3: Participants who agree to participate in this study will receive a monetary incentive of up to $310 per dyad (in VISA gift cards). The compensation will be divided into four portions such that:

$75 gift card will be given at the completion of T1 (baseline assessment), after completion of the 10 days of actigraphy and sleep diary). Gift card will be mailed to participant home.

$110 gift card will be given after T2 (immediately post SLEEPSMART intervention). Gift card will be mailed to participant home.

$125 gift card will be given after T3 (1 month after intervention) and 10 days of actigraphy and sleep diary). Gift card will be mailed to participant home.

**4.5 Non-monetary compensation**. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A

**4.6 Consent for recruiting and screening**. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

*"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.*

*Examples:*

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

☐ **No** → If no, you must still answer question **4.7** below.
☒ **Yes** → If yes, describe the consent process.

We will not obtain consent for pre-screening medical records for eligibility and PHI (diagnosis, name, contact information etc.)

Aim 1 & 2: Potential study subjects will respond to a letter by calling (or in person during the clinic visit) with the CRA. The CRA will complete a screening process to determine if subjects meet eligibility requirements

Aim 3: Potential study subjects will respond to the CRA by a telephone call or email. . The CRA will complete a screening process to determine if subjects meet eligibility requirements and/or participants will opt-in for screening procedures via https://www.sleepsmartstudy.org/webpage . If they have questions, they are advised to contact the CRA, who will follow-up by phone using the Recruitment Script and answer any questions.

**a**. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

☒ **No** → If no, describe the information you will provide during the consent process and for which procedures.

Aim 3: Participants will opt-in for screening procedures via https://www.sleepsmartstudy.org/webpage . If they have questions, they are advised to contact the CRA, who will follow-up by phone using the Recruitment Script and answer any questions.

☐ **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

**4.7 Data and specimens for recruiting and screening**. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain for recruiting and screening (prior to obtaining consent) and whether you will retain it as part of the study data.

***Obtain*** *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time.*

*Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.*

Screening information includes:
Parent first name, email address, phone number, and preferred mode of contact (text, phone, email) for follow-up. Also includes child first name, age, gender, and duration of JIA will be obtained to ensure study eligibility, and be retained as part of the study data. Additional information includes screening surveys: "does your child has difficulty with sleep quality and/or does poor sleep impact your child's day to day function?" and Sleep-Related Breathing Disorders, and parent report of child currently participating in psychological therapy.. These data will be stored via the secure REDCap database, accessible only by the study team.

## 5 PROCEDURES

**5.1 Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB* ***POLICY: Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*

During the pre-screening, the CRA will collect information from the medical records (age, JIA diagnosis, comorbid conditions, JIA disease duration, type of JIA, active or inactive disease).

**Aims 1 & 2**: 5 JIA children and their parent.

Phase 1-The initial 6-9 months will be for program development and beta testing of the sleep self-management intervention. First, we will conduct semi-structured interviews with open-ended questions with 10 JIA children and their parents to explore perceptions of poor sleep, facilitators and barriers to sleep, preferences and attitudes about technology to promote better sleep, the type of technology features users would or would not like, and what features would make sleep health tools acceptable to JIA children and parents and facilitate their use. Interviews will be conducted at a convenient time and place (in person or via phone), audio-recorded, and transcribed. The PI and Co-Is have prior experience in conducting and analyzing semi-structured interviews. Program content will be developed based on child and parent interviews, existing Web-based interventions for child with chronic pain and the current standard of care for sleep deficiency in children.

The interviews are expected to take 45 to 60 minutes, and we anticipate 2 to 3 interviews per family.

Phase 2: Beta testing. During months 8-9, we will beta test a prototype of the intervention with five JIA children and their parent. Participants will be videorecorded while interacting with the online modules (rate aspects of usability and satisfaction with features of the program) using their own smartphone, tablet, or computer, and describing what it is like having JIA and sleep problems.

The testing of the online modules are expected to take 45-60 minutes.

Aims 1 & 2 (total 6 to 9 months)

| | |
|---|---|
| Participate in 2 to 3 interviews at a convenient time and place (10 JIA parents and children)<br>○ interview questions would explore perceptions of poor sleep, facilitators and barriers to sleep, preferences and attitudes about technology to promote better sleep, the type of technology features you and your child would or would not like, and what features would make sleep health tools acceptable to JIA children and parents.<br>○ Each interview will take 45-60 minutes, and would be audio-recorded | Sept 2018- May 2019 |
| | |
| Test the online sleep-based program your own smartphone, tablet, or computer (5 JIA parents and children).<br>○ We would video record participants while interacting with the online modules and rating the usability and satisfaction of the online modules. We would also ask participants to describe what it is like having JIA and sleep problems.<br>○ We would like to share this video recording in an online intervention we want to develop to help children with JIA self-manage their sleep. See aim 3. Participants will have the option of opting out of the video recording. Participants will have an option to opt out of the videotaping.<br>○ We anticipate that the testing of the online modules would take 45-60 minutes. | April 2019- August 2019 |

**Aim 3:** A pilot feasibility RCT (Active treatment group [SLEEPSMART online module] vs. control group) is proposed to test the feasibility, acceptability, and initial efficacy of the new 6-week sleep self-management intervention with 60 children with JIA (8 to 13 years)) and their parents. Outcome assessments will occur at baseline (T1), immediately post intervention (8 weeks; T2), and 1 month post-intervention (T3). **Aims 3 will occur after Aims 1 and 2 are complete and will require a total of 3 months.**

Following completion of baseline assessments, participants will be randomized to one of two treatment groups (Active treatment [ SLEEPSMART] or control group). **Active treatment group will include 30 JIA children who will be randomized to the online sleep intervention (** SLEEPSMART**). Control group will include 30 JIA children who will not receive the online** SLEEPSMART **intervention.**

A blocked randomization scheme will be generated using an online program will be used to derive randomization assignment, programmed in the internet sleep intervention, and not accessible to study investigators. Enrolled participants will be continuously randomized

**T1 BASELINE ASSESSMENT**

A member of the research team will connect with eligible and interested participant children and their parent at convenient time, will talk about the purpose of the study, and obtain consent from parent/caregiver participants (see SLEEPSMART Consent in Appendix A). Child assent will then be obtained and copies of both documents given to the parent (see SLEEPSMART Assent in Appendix A).

After consent and assent, JIA children and their parent will be given a link with the electronic instruments preloaded and instructed to complete the instruments to the best of their ability. If questions arise, a member of the research team will answer as needed. This technique was successfully used in Dr. Ward and Palermo's prior intervention studies. The surveys for T1, T2, and T3 will take 30 to 35 minutes to complete.

**Table 1. Summary of T Assessments – All T1, T2, and T3 unless otherwise indicated (T1 [Baseline], T2 [immediately post intervention], T3 [1 month post intervention])**

| Parent Items | Estimated Time (minutes)/ Assessment | Child Items | Estimated Time (minutes) |
|---|---|---|---|
| Demographics<br>(age, gender, race, ethnicity, income; child age, race, ethnicity; medications)<br>Childhood assessment questionnaire | 5<br>T1<br><br><br>T1 | | |
| Self-management measures<br>Self-efficacy to Manage Chronic Disease Scale<br>Decision Balance sheet<br>Goal setting (# and types of goals created of goals tracked and rate of goalsCredibility/Expectancy Questionnaire | <5 | Self-management measures<br>Child Self-efficacy Scale<br>Patient activation measure<br>Index of self-regulation<br>Goal setting (# and types of goals created of goals tracked and rate of goals<br>Sleep problems questionnaire | <5 |
| SYMPTOMS<br>PROMIS 29 profile<br>PROMIS Sleep disturbance -adult<br>PROMIS sleep-related impairment | <5 | SYMPTOMS<br>PROMIS Peds Profile (physical function, anxiety, depression, fatigue, peer relationships, pain interference).<br>PROMIS Sleep disturbance<br><br>PedsQL Multidimensional Fatigue | 10 |
| Children's Sleep Hygiene Scale<br>Children's Sleep Wake scale<br>Children's Sleep Habits Questionnaire<br>Dysfunctional Beliefs about sleep scale<br>Pittsburgh sleep quality index | 15<br><br><br><br><br>T1 | Adolescent Sleep Hygiene Scale<br>Adolescents Sleep Wake scale<br>Dysfunctional Beliefs about sleep scale<br>Pre-Sleep Arousal Scale<br>Morning Eveningness questionnaire | 15<br><br><br><br><br>T1<br>T1 |
| Health Outcomes<br>PROMIS Global Health<br>PedsQL Family Impact Module<br>Health Care Utilization | 5 | Health Outcomes<br>Health-related Quality of Life Questionnaire<br>PROMIS Global health | 5 |
| Treatment Evaluation Inventory (Acceptability)<br>Sleepsmart end of Survey | <5<br>T3<br><br>T3 | Treatment Evaluation Inventory (Acceptability<br>Sleepsmart end of Survey | <5<br>T3<br><br>T3 |

**Actigraphy** After completing the above instruments at baseline, a member of the research team will give the parent and child the actigraph. The actigraph will be worn by children and parents (on non-dominant wrist) continuously for 10 days. Both will be instructed in the application of the monitors including removal during bathing, swimming, and how to assess for appropriate fit using the monitor band. Both will be instructed to document times when the actigraphy monitor is removed and replaced using the diary. Actigraphs will be

collected at the end of the 10 days of recording using a prepaid padded envelope. Sleep variables obtained via actigraphy include sleep onset, sleep offset, sleep period time, mean activity during sleep, mean number of minutes of sleep and wake, percentage of sleep and wake within the sleep period, and number of waking episodes during the sleep period. These variables are used to derive total sleep time, percent sleep efficiency (SE, sleep time/time in bed x 100), percent wake after sleep onset (WASO, wake min/sleep time x 100), and a fragmentation index (of waking episodes/hr). These variables will enable us to reliably characterize sleep quality as it is occurring in the home environment.

**Electronic Sleep Diary (wake time and bedtime)**

Parents and children will record their daily sleep. A standard log of sleep activities (time to bed, sleep onset, awakenings, quality) will be completed daily in the morning upon awakening and prior to bedtime using a previously established and tested sleep diary.

SLEEPSMART **INTERVENTION (ONLY Treatment group receives this)**

2-3 weeks after parent/caregiver and child actigraphs are returned and analyzed by a member of the team, a phone meeting will be schedule at a convenient time for the participants. A member of the team will provide written and verbal feedback to the child and their parent about their sleep. Based on this assessment, one of three web-based modules will be assigned.

**Table 2.** SLEEPSMART **Modules**

| Module | Goals | Strategies |
|---|---|---|
| Bedtime routine | Structured, consistent bedtime routine ≤ 30 minutes in length and implemented consistently | Family develops tailored routine, uses bedtime chart to maintain routine, problem-solving around barriers to routine |
| Sleep Quality | Sleep scheduling to allow for 9-11 hours of nighttime sleep (child) or 7-9 hours (parent); sleep onset-falls asleep within 30 minutes, minimal nighttime awakenings. | Family sets sleep/wake schedule that allows for enough sleep; strategies for decreasing sleep disruptions/awakenings; problem-solving around barriers to routine. |
| Sleep Environment | Creating sleep environment conducive to sleep – minimize noise, light, media exposure. | Family develops quiet, dark sleep environment, decreases nighttime media; problem-solving around barriers to routine. |

A member of the team will instruct the family on how to access the SLEEPSMART website and their assigned module. Children will be instructed to log on once per week to the website to complete a module and assignment, designed to take about 30 minutes to complete. The SLEEPSMART assigned modules will begin with an educational module, then direct participants through goal setting, anticipated barriers, and problem solving. Web pages will include fillable responses to queries, instructions, and assignments. Tasks for children will use multimedia elements to enhance delivery of information, such as links to videos and pictures targeting self-efficacy, motivation, and patient activation. The materials used will be modified from an existing intervention, Sleep Habits in Preschoolers (SHIP), which has been pilot tested and has enrolled 450 typical developing preschool children and their parents (PI: Ward).

Submissions and progress will be monitored by a member of the research team, who will send email, call or text with reminders (whichever the family prefers) and answer questions as needed, review progress, and help problem solve any technology issues or barriers to implementing skills. This online structure and feedback process is modeled after the work by Dr. Palermo, Co-I on this grant, who has successfully implemented web-based interventions with parents and children.

## T2 – IMMEDIATELY FOLLOWING INTERVENTION ASSESSMENT

At the end of the 6-week SLEEPSMART intervention, for both the treatment and control groups will be mailed actiwatches, and parents and children will wear for 10 days. They will also complete the daily sleep

diary as described before. Actigraphs and sleep diaries will be returned via prepaid envelopes. Plus the above questionnaires in Table 2.

**T3 – 1 MONTH following baseline**

For both the treatment and control groups, actiwatches will be mailed to parent/child participants to wear for 10 days. They will also complete the daily sleep diary as described before. Actigraphs and sleep diaries will be returned via prepaid envelopes. Parents and children will individually complete the instruments/research items below, nearly identical to T0 baseline visit with the exception of removing the demographic questionnaire, and use of health care utilization survey (exit) for parents and the SLEEPSMART Acceptability Questionnaire. The parent/caregiver will be given a link with the electronic instruments preloaded and instructed to complete the instruments to the best of their ability. If questions arise, a member of the research team will answer as needed. After completing the below listed activities, parent and child participants will interviewed together using semi-structured interview questions to assess participant acceptability of the SLEEPSMART Study.

| | | | |
|---|---|---|---|
| | | | |

**5. 2 Data variables.** Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

**Screening**

Parent report of yes to either of the following questions: "does your child has difficulty with sleep quality and/or does poor sleep impact your child's day-to-day function (school, interacting with peers, hobbies)?" **Pediatric Sleep Questionnaire (PSQ) Sleep Related Breathing Disordered Scale**

22-item using 3 point scale (yes = 1, no= 0, don't know = missing). Number "yes" items divided by total number of items responded, with scores ranging from 0-1. Scores >0.33 considered positive and suggestive of high risk for a pediatric sleep-related breathing disorder.

Does your child currently receive psychological therapy?

**Enrolled subject data to be collected**

| Concept | Measure |
|---|---|
| **Demographics** | Parent-report survey includes information about parental characteristics (age, gender, education, race, ethnicity, household income) and child characteristics (age, gender, grade level, race, ethnicity, JIA type, and medications).<br><br>**Child Health Assessment Questionnaire**-parent report measure that assesses daily activities and functional impairment due to chronic pain in child. |
| **Self-Management Measures (treatment group only)** | **Self-Efficacy-** 9-item parent & 5-item children report of their confidence in carrying out sleep-related behaviors using 10-point Likert scale (1=not confident at all, 10=totally confident). Higher scores indicate higher self-efficacy.<br>**Index of self-regulation**- 12-item parents & child report of motivation (recondition, stimulus control, behavioral monitoring)<br>**Patient activation measure**- 13-item parent & child report of knowledge, skill, & confidence for self-management.<br>Goal Setting: engagement in goal setting will be tracked on the SLEEPSMART web-based application using # and type of goals created; # of goals tracked; and rate of goal completion.<br>Sleep Problem questionnaire- 4 item child report of their readiness to change their sleep habits.<br>Credibility /expectations Questionnaire: 6-item parent report questionnaire to rate treatment expectancy |

| | |
|---|---|
| **Sleep** | |
| | **Child Sleep Habits Questionnaire (CSHQ)** 45-item retrospective report of child sleep habits over typical week using 3 point Likert scale. Higher scores indicate greater likelihood of sleep disturbance, with >41 as the cut-point for clinically significant sleep disturbance. Eight sleep subscales include bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night awakenings, parasomnias, sleep-disordered breathing, and daytime sleepiness. |
| | **Children's /Adolescent Sleep Wake Scale** – 25-item child report measure of sleep quality over the last month; includes 5 domains: going to bed, falling asleep, maintaining sleep, reinitiating sleep, and returning to wakefulness. A total score indicates overall perception of sleep quality |
| | **Children's Sleep Hygiene Scale** – 17- item parent report measure of sleep hygiene (habits) over the past month; includes 8 subscale scores (physiological factor, behavioral arousal factor, cognitive/emotional factor, sleep environment factor, sleep stability factor, daytime sleep factor, substances factor, bedtime routine factor; yields a total score (higher scores indicative of better sleep hygiene)<br>**Adolescent Sleep Hygiene Scale**- 28 items adolescent report of sleep habits over the past 1 month; includes 9 domain scores; |
| | **Pre-Sleep Arousal Scale**- 16 item child report of somatic arousal (e.g., "cold feeling in your hands, feet or your body in general"), cognitive arousal (e.g., "worry about falling asleep"). |
| | **Dysfunctional beliefs and attitudes about sleep**- 10-item child and parent report measure of beliefs about sleep (a) beliefs that are uncontrollable and unpredictable; (b) unrealistic sleep expectations; (c) misconceptions about the causes; (d) erroneous beliefs about sleep-promoting habits; (e) dysfunctional beliefs about the consequences. Compute the average of all completed16 items. A higher score reflects greater dysfunctional beliefs about sleep. Target beliefs expressed in items with scores > 5. |
| | **Morning/evening scale for children**- 10-item child report that measures when you consider "feeling best" and indicate preferred clock time blocks for sleep and engagement in various situations (e.g., physical exercise, tests, school, work), in addition to assessing morning alertness, morning appetite, evening tiredness, and alarm clock dependency. MEQ scores can range from 16 to 86, with lower scores indicating evening types and higher scores indicating morning types.<br>**Pittsburgh Sleep Quality Index (PSQI)-** 19-item parent report measure to assess sleep quality and usual sleep habits over the previous month. PSQI yields subscale scores for sleep quality, latency, duration, sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. Survey items are rated on a 0-3 Likert scale, with higher scores indicating poor sleep quality and poor sleep habits. |
| **PROMIS** | |
| PROMIS Physical Functioning, fatigue, anxiety, depression, peer relationships, pain interference | **PROMIS Pediatric profile**- child report of physical function, fatigue, anxiety (6 items that tap into fear [fearfulness, worry], depressive symptoms [negative mood [sadness, guilt], peer relationships [quality of relationships with friends and other acquaintances] , pain interference (pain interfering with routine activities over the past 7 days and one single pain intensity item (average pain intensity over the past 7 days)<br>PROMIS 29 profile- 29-item parent report of physical function, fatigue, anxiety, and depression.<br>**Peds QL Multidimensional Fatigue Scale** 18-item *child repor*t of fatigue in last month; yields 3 subscale (general fatigue, sleep/rest fatigue, cognitive fatigue) & total fatigue score.<br>**PROMIS Sleep disturbance- -** 8-item child and parent report of self-reported perceptions of sleep quality, depth, and restoration (e.g., perceived difficulties falling asleep and staying asleep, sleep satisfaction) within r the past 7 days; higher scores indicate greater sleep/wake disturbance<br>**PROMIS Sleep-related impairment**- 8-item child and parent report of self-reported alertness, sleepiness, tiredness, and functional impairments associated with sleep |

| | |
|---|---|
| | problems during waking hours within the past 7 days; higher scores indicate more impaired alrterness |
| **Health Outcomes**<br>Global Health<br><br><br><br><br><br><br><br>Family Function<br><br>Health Care Utilization | **Pediatric Quality of Life Inventory -**13 item child report of physical functioning, emotional functioning, social functioning, and school functioning over the past 7 days. Total HRQOL, and two summary scores (Physical Health and Psychosocial Health), with higher scores indicating better QoL.<br>**PROMIS Global Health** – child and parent report of overall health and well-being. Scores in each dimension are summed per outlined manual protocols.<br><br>.<br>**Pediatric Quality of Life Family Impact Module** (parent) 36-item *parent*-report measure of family function over the last month. Domains include: 1) Physical Function, 2) Emotional Function, 3) Social Function, 4) Cognitive Function, 5) Communication, 6) Worry, 7) Daily Activities, and 8) Family Relationships; Items are summed and scaled to calculate a total and family functioning score (higher scores indicate better functioning).<br><br>5-item parent report tool comprised of yes/no questions related to seeking health care on behalf of self and/or child. |
| Actigraphy | Actiwatch 64 Small wrist watch that measures body movement and estimates of total sleep time, amount of wake, sleep quality, bedtime and waketime variability. |
| Sleep diary | Electronic daily sleep and pain diary-children and parents will complete an electronic sleep diary twice a day for 10 days. Children and parents will complete the diary at bedtime and upon waking (what time you went to bed, wake up, # and duration of night awakenings), events that may disrupt your sleep (anxious about a test; hobbies [music recital, basketball game, school event], parent out of town, fight with a friend, homework, sickness). |

Below questionnaires to be completed by treatment group only:
Treatment Evaluation Inventory and End of Study Survey **Acceptability Survey** only the treatment group will complete this survey. 11-item survey to be used in post-intervention interview with parent and child. Survey includes 6 open-ended questions and 5 Likert scale questions (1=strongly disagree, 5=strongly agree). Items assess participant acceptability of various components of the SLEEPSMART Study.

**5.3 Data sources.** For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

*If you have already provided this information in Question 5.1, you do not need to repeat the information here.*

Data will be obtained from the child and parents in the form of:
Aims 1 & 2: semi-structured interviews, & videotaping, and testing of the REDCap SLEEPSMART Website use – site tracks unique ID logon date, time, duration;
Aim 3: surveys (REDCap), sleep diaries (REDCap), and wrist watch. REDCap SLEEPSMART Website use – site tracks unique ID logon date, time, duration.

The CRA at SCH will collect information from the child's medical record (name, age, sex, phone number, address), JIA form (disease duration, onset of symptoms, JIA type, active or inactive disease ). The research staff at CHOP will not collect this information, rather parents will complete demographic survey that includes child age, gender, disease duration, JIA type, and active or inactive disease.

**5.4 Retrospective/prospective.** For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist at the time when you submit this application)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

Aims 1 &2: We will collect all prospective data, though semi-structured interviews, video recording, self-report data may include retrospective recall via medical charts (e.g. , age, JIA diagnosis).

**5.5 Identifiability of data and specimens**. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

*__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
*__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
*__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.*
*__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
*__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
*__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.*

**a.** Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

The CRA, staff at CHOP, RA, and PI will have access to direct identifiers: medical charts to determine participant eligibility (name, age, address, phone number, sex, JIA diagnosis); and the PI and the team will have access to indirect identifiers: participant code.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

*You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

**b.** Will you <u>obtain</u> any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

The CRA at SCH and staff at CHOP will obtain direct identifiers from medical charts to determine participant eligibility (name, age, sex, address, phone number, JIA diagnosis).

Parent: Legal first, middle (if applicable), last name; date of birth; city/country of birth; gender at birth; parent email address; telephone number; home address; for study communication, study mailings

SLEEPSMART website will track IP address for website login dates, usage

Child: Legal first, middle (if applicable), last name; date of birth; city/country of birth; gender at birth;

SLEEPSMART website will track IP address for website login dates, usage

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

*You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

**c.** If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

☐ You will store the identifiers with the data. Describe the data to which this applies:

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Study participants will be assigned a number in the order they enroll in the study. The link between the participant identify and study code number (a written list) will kept in

the CRA's locked office in a locked file, separate from the data collected during the course of the study and participant identity.

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

**d. Research collaboration**. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

*Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.*

The CRA who works in the Pediatric Rheumatology clinic at SCH and research staff at CHOP Pediatric Rheumatology clinic, will review medical record for participant eligibility and assist with participant recruitment will have access to direct identifiers. The PI will also have access to direct identifiers. Drs. Tonya Palermo & Sarah Ringold, who work at SCH will be involved in 1) study, interpretation, or analysis of the data that results from the coded information; and (2) authorship on presentations or manuscripts related to this work.

**5.6 Newborn dried blood spots.** Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

☒ **No**

☐ **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

☐ **No**

☐ **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

**5.7 Protected Health Information (PHI).** Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

*PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.*

☐ **No** → If no, skip the rest of this question; go to question **5.8**

☐ **Yes** → If yes, answer all of the questions below.

**a.** Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

The CRA and the staff at CHOP will not obtain consent to obtain information from the child's medical chart - name, age, sex, phone number, address, JIA diagnosis, to identify potential eligible subjects.

**b.** Is any of the PHI located in Washington State?

☐ **No**

☒ **Yes**

**c.** Describe how you will access or obtain the PHI. *Be specific.*

The CRA at SCH and the staff at CHOP will be the only member of the team who will have access to the medical records to determine participant eligibility. The CRA at SCH and staff at CHOP- who works in the Pediatric Rheumatology clinic, will recruit potential subjects and review the medical charts because she will need the above PHI for study eligibility.

**d.** For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

☐ **Confirmed**

**e**. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Name, age, sex, address, JIA diagnosis

Provide the following assurances by checking the boxes.

☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☒ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

**5.8 Genomic data sharing**. Will you obtain or generate genomic data (as defined at *https://gds.nih.gov/13faqs_gds.html*)?

☒ **No**

☐ **Yes** → If yes, answer the question below.

**a.** Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

☐ **No**

☐ **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

**5.9 Data and specimen sharing/banking**. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

*Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.*

☐ **No**

☒ **Yes** → If yes, answer all of the questions below.

**a.** Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

**Aim 3 only**
Funding requires use of NIH common data elements Biomedical Research Informatics Computing System (BRICS). This system uses a computer program that researchers download onto their university computer. Researchers then enter subject personally identifiable information to derive a series of one-way hashes which securely encrypt the subject information. One way hashes are sent to the GUID server for reference and storage. No personally identifiable information is sent to the system. The GUID server returns a GUID identifier. If the one way hashes match a known subject, an existing GUID will be returned; if it is a new subject, a new GUID will be returned. PI will store GUIDs for subjects.

**b.** Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

**Aim 3 only**
Once the researcher has a GUID, s/he may submit data associated with this subject. Researchers are then able to access data in the BRICS database across studies without revealing personally identifiable information. Use of GUID is required by the NIH/NINR funding mechanism for this study.
Common Data Elements shared will not contain PHI, but rather the GUID, and relate to parent-reported PROMIS measures (sleep disturbance, global health, fatigue, anxiety, depression scores). At this time, no plan to share child common data elements.

**c.** Who will oversee and/or manage the sharing?

Common data elements will be accessible by researchers to potentially pool and analyze data across studies.

**d.** Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

*Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.*

**e.** Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

[ ] **No**
[X] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 6.

**f.** Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

[X] **No**
[ ] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

*Example: data can be withdrawn from the repository but cannot be retrieved after they are released.*

**g.** Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

*Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them*

[X] **Confirmed**

**5.10 Communication with subjects during the study**. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

*Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.*

Email, letter to eligible participants about the study; phone calls about reminders for the interview, to wear the watch, completing surveys on REDCap, and returning the watch in a prepaid envelope.

**5.11 Future contact with subjects**. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[ ] **No**
[x] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

*Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.*

Consent includes section where parent may opt in/out of retaining contact information for future research studies. If they opt in, subject provides preferred method of contact (phone, email, mailing address). If opt in, information will be stored on PI's secure network and accessible only to the PI and her research team. This procedure was successful in our prior studies.

**5.12 Alternatives to participation.** Are there any alternative procedures or treatments that might be advantageous to the subjects?

*If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.*

[x] **No**
[ ] **Yes** → If yes, describe the alternatives.

**5.13 Upload to the Supporting Documents** SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

Short written descriptions of materials that cannot be uploaded, such as URLs

A description of the process you will use for data that will be gathered in an evolving way.

- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

Primary data collection method will be via semi-structure interviews (Aims 1 & 2), and REDCap surveys – PDF versions of these surveys will be attached (Aim 3).

**5.14 Send HSD a Confidentiality Agreement** if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

*The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.*

## 6 CHILDREN (MINORS) and PARENTAL PERMISSION

**6.1 Involvement of minors**. Does your research include minors (children)?

**Minor or child** means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.

There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.

The generic age of consent may be different in other states, and in other countries.

☐ **No** → If no, go to Section 8.

☒ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

8-13 YEARS

☐ **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

**6.2 Parental permission. Parental permission** means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

**a.** Will you obtain parental permission for:

☒ All of your research procedures → Go to question **6.2b.**

☐ None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

*Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.*

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission | Reason why you will not obtain parental permission | Will you inform them about the research?[2] YES | NO |
|---|---|---|---|---|
| N/A | N/A | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |

| | | |
|---|---|---|
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |

*Table footnotes*

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

**b.** Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☒ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

*This is all that is required for minimal risk research.*

If you checked both boxes, explain:

Research is minimal risk, one parent will provide consent.

**6.3 Children who are wards.** Will any of the children be wards of the State or any other agency, institution, or entity?

☒ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

Background and experience

Willingness to act in the best interests of the child for the duration of the research

Independence of the research, research team, and any guardian organization

## 7 ASSENT OF CHILDREN (MINORS)

*Go to Section 8 if your research does not involve children (minors).*

**7.1 Assent of children (minors)**. Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

**a.** Will you obtain assent for:

☒ All of your research procedures and child groups → Go to question **7.2.**

☐ None of your research procedures and child groups → Use the table below to provide your justification, then skip to question 7.5.

☐ Some of your research procedures and child groups → Use the table below to identify the procedures for which you will not obtain assent.

*Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.*

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained | Reason why you will not obtain assent |
|---|---|---|
| N/A | Consent and Assent will be obtained verbally & electronically. | |
| | | |
| | | |
| | | |
| | | |

*Table footnotes*

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

**7.2 Assent process.** Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

Following parental consent, a research team member will read the assent form to the child with the parent nearby- either on the phone or in person at the clinic visit. The CRA will answer any questions, and will emphasize that participation is voluntary, and they can stop anytime. All participants will provide assent verbally and electronically thru REDcap. The parent will be provided a copy of the assent form. Participants will be given the opportunity to ask questions of the CRA over the telephone, and/or in the presence of their parent/legal representative.

**7.3 Dissent or resistance.** Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

We will remind participants that no one will be mad at them if they chose not to participate or complete the study, and we will ask whether the participant is comfortable with participation prior to beginning the study procedures, and during the study procedures. We will invite questions from the participants, and efforts to clarify and simplify the research and participants' roles will be prioritized, as well as providing reminders that research participants always retain the right to withdraw from the study at any time.

**7.4 Documentation of assent.** Which of the following statements describes whether you will obtain documentation of assent?

☒ None of your research procedures and child groups → Use the table below to provide your justification, then go to question 7.4.a.

☐ All of your research procedures and child groups → Go to question **7.4.a**, do not complete the table

☐ Some of your research procedures and/or child groups

→ Complete the table below and then to go question 7.4.a

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented | Reason why you will not document assent |
|---|---|---|
| Children and parents | We are not obtaining an ink signature for subjects assent | Verbal and electronic (RECap) assent will be documented |
| | | |
| | | |
| | | |
| | | |

*Table footnotes*

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

**a. Describe how you will document assent**. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

Assent for child and parents will be obtained verbally and electronically thru a secured link (REDCap). Study eligibility for participants includes understanding and speaking English because the surveys have not been translated into other languages, and given we are asking child to respond to the surveys—literacy is needed. Thus participants who are not fluent in English and/or functionally illiterate are not eligible for the study.

**b. Upload all assent materials** (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

**7.5 Children who reach the legal age of consent during participation in longitudinal research.**

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

**a.** Describe your plans (if any) to re-obtain assent from children.

We will not re-obtain assent from participants.

**b.** Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.

If you do not plan to obtain consent or think that you will be unable to do so, explain why.

N/A

**7.6 Other regulatory requirements**. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

PPRA – Protection of Pupil Rights Amendment

FERPA – Family Education Rights and Privacy Act

COPPA – Children's Online Privacy Protection Act

## 8 CONSENT OF ADULTS

**Review the following definitions before answering the questions in this section.**

| | |
|---|---|
| **CONSENT** | is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process. |
| **CONSENT DOCUMENTATION** | refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form. |
| **CONSENT FORM** | is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process. |
| **ELEMENTS OF CONSENT** | are specific information that is required to be provided to subjects. |
| **PARENTAL PERMISSION** | is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements. |
| **SHORT FORM CONSENT** | is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available. |
| **WAIVER OF CONSENT** | means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. |
| **WAIVER OF DOCUMENTATION OF CONSENT** | means that there is IRB approval for not obtaining written documentation of consent. |

**8.1 Groups** Identify the groups to which your answers in this section apply.

[X] Adult subjects

[x] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

**8.2 The consent process**. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

*The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.*

**a**. Are there any procedures for which you will not obtain consent?

[x] **No**
[ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

*Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.*

| Group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO consent process | Reason why you will not obtain consent | Will you provide subjects with info about the research after they finish? YES | NO |
|---|---|---|---|---|
| N/A | N/A | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |

*Table footnotes*

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

**b.** Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

*Be sure to include:*

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

The CRA at SCH will meet with potential parent participants over the phone at a convenient time. There, she will describe the study, answering any questions, and emphasize that their participation is voluntary. Participants may ask questions any time. Should the CRA be unable to answer these questions, they will be referred to the PI who will then communicate the answers back to the potential participant and allow ample

time for any questions. Parental permission and consent will be obtained verbally and electronically through REDCap. All participants will receive a copy of the signed consent.

Participants recruited from CHOP will contact the CRA directly via email or phone to learn more about the study.

**c.** Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

Ask if the subject has any questions. Ask the subject to review the basic study procedure, providing prompts if needed (baseline visits, study duration, follow-up visits). Intervention involves weekly online activities.

We will ask the participants to describe the study in their own words. Assessment of the potential child's understanding of the research and what is expected of them will be done by asking child to describe in their own words what they would do if they agreed to participate. For example, please tell me why we are having your wear a wristwatch? In addition, CRA and/or PI can assess how well participants understand the study through the types of questions, and appropriateness of questions, raised by participants during discussions related to the study.

**d.** Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

*Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.*

☐ **No**

☒ **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

*Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.*

Participants will use electronic consent and assent via REDCap. The CRA at SCH will obtain consent instead of the participant's physician.

**e.** Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

Prior to any subject interaction, parents and children will be asked if they have any questions or concerns about participating. They will be reminded that they may stop at any time. During online participation, written prompts remind that they may stop at any time.

**8.3 Written documentation of consent.** Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

*Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent*

**a.** Are you obtaining written documentation of consent for:

☒ None of your research procedures → Use the table below to provide your justification then go to question **8.4.**

☐ All of your research procedures → Do not complete the table; go to question **8.4.**

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

| Adult subject group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent | Will you provide them with a written statement describing the research (optional)? YES | NO |
|---|---|---|---|
| N/A | N/A | ☐ | ☐ |
| JIA children and parents | ***parental permission and parental consent verbally and electronically through REDCap.*** | x | ☐ |
| | | x | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |

*Table footnotes*

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

**8.4 Non-English-speaking or -reading adult subjects**. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

**a.** Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

**b.** Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

**8.5 Barriers to written documentation of consent**. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

**a.** Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

*Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person; excluding individuals who cannot read and understand the consent form.*

We will exclude participants who cannot read and understand the consent form because we are interested in child's responses about sleep and symptoms. Thus understanding of English is required.

**8.6 Deception**. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

[x] **No**
[ ] **Yes** → If yes, describe what information and why.

*Example: you may wish to deceive subjects about the purpose of the study.*

**a.** Will you debrief the subjects later? (Note: this is not required.)

[ ] **No**
[ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

**8.7 Cognitively impaired adults, and other adults unable to consent.**

**a.** **Cognitively impaired adults and other adults unable to consent**. Do you plan to include such individuals in your research?

*Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.*

[x] **No** → If no, go to question **8.8**.
[ ] **Yes** → If yes, answer the following questions.

**a.1.** Rationale. Provide your rationale for including this population in your research.

**a.2.** Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will re-assess decision-making capacity and consent during that time.

**a.3.** Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

**a.4**. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

**a.5.** Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

**8.8 Consent-related materials**. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

## 9 PRIVACY AND CONFIDENTIALITY

**9.1 Privacy protections.** Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

*Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.*
*Examples:*

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

Some participants may feel a violation of privacy if they receive a letter asking them to participate in a study because their child has JIA, when their name, contact information, and medical condition were drawn from medical records without their consent. Eligible participants will receive a phone call and/or a letter asking them to participate in this study because they have a child with JIA.
This research will gather several types of sensitive information, around which special care must be taken. We will take measures to ensure that this information is handled appropriately, safely, and only for the scope of this research. There are additional privacy and confidentiality concerns with reporting health-related information in the study.
**Loss of Privacy**: Participants will be informed that their information will be kept confidential. Participant confidentiality will be protected by using a study identification number on all records. The audio-recorded interviews and videorecording with the participant's study specific identification number and stored on a separate password-protected, secure server at the SON. Participants' contact information will also be stored separate from study data and identifying numbers in a file on a password-protected server. All electronic data will be stored on password-protected servers and all identifying information will be deleted from the qualitative interviews during the transcription process. The wrist watch device will not contain any private or confidential information and will be linked to the participant only through the unique study identification number. Information will be compiled from all the participants in the study and, when published, data will be reported in aggregate form. As a result of aggregation, no individual participants will be identifiable from the written materials.

Data collection forms used during the study will be surveys and identified only by assigned code number. Participants will complete sleep diaries through the web-based electronic data capture interface, which is password-protected and encrypted (no direct identifiers will be present among the electronic data). Research paper forms will be kept in a locked file cabinet in CRA's office separate from the consent forms and code list, available only to authorized research colleagues assisting with data analysis. No participants will be identified in any report or publication about this study. Data collected via surveys using the iPad will use REDCap, which is password protected and encrypted, with no direct identifies present among electronic data.

The protection of human subjects in the proposed study is ensured through control of access to the data, maintenance of locked files for data and consent forms, and careful training and supervision of all research personnel. Subject identifying information will be accessible only to study personnel with appropriate access privileges and will be kept in a locked office in a locked file, separate from other study materials. Electronic data will be stored on a secure server that requires password access form a computer with a registered domain to gain entry.

Risk of unauthorized disclosure of an individual's data to others outside of the study personnel is possible. To protect information, we will keep subject names or any number that could identify them separate from study data. Subjects will be assigned codes and individual access to SLEEPSMART web materials.

**9.2 Identification of individuals in publications and presentations**. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[ ] **No**
[x] **Yes** → If yes, will you obtain subject consent for this use?
  [x] **Yes**
  [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

With child and parent permission, we will share the video recording in an online intervention that we would like to develop (see Aim 3) to help JIA children self-manage their sleep. Participants will have the option of opting out of the video recording.

**9.3 State mandatory reporting.** Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

Child abuse

Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult

Sexual assault

Serious physical assault

Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[ ] **No**
[x] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

**9.4 Retention of identifiers and data.** Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

*This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)*

*See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):*
***http://f2.washington.edu/fm/recmgt/gs/research?title=R***

*See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records:* ***http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf***

[x] **Confirm**

**9.5 Certificates of Confidentiality**. Do you have or, are you planning to obtain, a federal Certificate of Confidentiality for your research data?

[x] **No**
[ ] **Yes**

**9.6 Data and specimen security protections**. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

**a.** Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

**LEVEL 3 DATA.** These data could result in harm that can have genuine impact, but the magnitude and/or duration are generally not serious, long-lasting, and/or irreversible.

**b.** Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels.

## 10 RISK / BENEFIT ASSESSMENT

**10.1 Anticipated risks**. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Potential Risks: There are potential risks around anxiety related to the interviews, video recording, time commitment, possible mild skin irritation from the actigraphy, and confidentiality. Although asking questions about what helps you sleep and what keep you up at night, and questions about anxiety, depression, pain, fatigue, and global health does not typically result in increased distress in the participant, emotional distress is a potential risk. We have used all of the proposed measures in our previous studies without any untoward effects. In the course of the study, we may become aware of symptoms of depression. There is some indication that child with JIA have increased depressive symptoms although data does not suggest that they have increased rates of suicidal ideation. Our measure of depressive symptoms (PROMIS measure) does not assess suicidality. However, a child may disclose such information in their communication with research team. The Research team is trained to carefully monitor such issues (see Suicidal Ideation Assessment Plan below). There should be minimal

discomfort related to the length of the assessments. Total time burden is estimated at 30 minutes for parents and child.

**Protection against Risk**

**Informed Consent**: Participants who meet eligibility criteria and want to participate will complete informed consent and pre-treatment measures via the phone and Research Electronic Data Capture (REDCap), a secure web-based tracking and on-line data acquisition system. All of the study procedures will be explained at that time over the phone as well as the potential risks and benefits of participation. Child and parents will be able to ask questions about participation and have them answered. Consent, assent and HIPAA forms will be available online for participants to view and save for their records. Similar to procedures in our prior studies, these forms will be reviewed over the phone and verbal assent and consent will be obtained and documented per the UW IRB. Names and phone numbers of the PI and the UW Institutional Review Board are provided in these consent forms. Screening for study eligibility involves questions about age, SLE diagnosis, and whether the parent and child speak and understand English.

**Time Commitment**. Participant burden, specifically time commitment, is the most likely risk related to this study. For aims 1 & 2 we anticipate screening and consent to take 30 minutes, and the interviews to take 45 to 60 minutes each, and 45 to 60 minutes to videorecord and interact with the online modules. For Aim 3, we anticipate screening to take screening and consent to take 10 minutes, and 30 to 35 minutes for parents and children to complete the surveys per assessment. To minimize subject burden during data collection, we chose only the most relevant instruments for sleep, self-management, daytime function, health outcomes, and demographic and clinical data. In order to reduce subject burden from the length of the data collection, we will allow participants to complete questionnaires at their convenience on REDCap. REDCap is designed so that participants can save their information, log off and return to it at any time. These data are safeguarded as soon as they are entered providing protection against privacy risk even if all measures are not completed at one time. Subjects will receive modest financial compensation (gift cards) for the time commitment necessary for their study participation. There will be no cost to the subject, parent, or their insurance company for participation in the study.

**Anxiety**. To help reduce any discomfort about semi-structured interview questions about sleep or answering questions about self-report measures, the research protocol includes standardized measures that have been widely used in other research without adverse effects. Prior to initiating the semi-structured interview questions participants will be reminded that the interview will take between 45 and 60 minutes to complete. If participants experience stress or discomfort in response to interview questions, the interview will be discontinued to tend to the participant's emotional needs. Prior to video recording, the participants will be reminded that the video recording may take between 45 -60 minutes. If participants experience stress or discomfort in response to the video recording, participants will have an option of not being video recorded  Data collection will resume if and when the participant is ready to proceed or delayed until a later date. We will be very clear with participants that their comfort takes precedence. In cases where the interview needs to be delayed due to discomfort, that will be noted. Self-report questionnaires are routinely used in research, and pose no risks.

Although asking about sleep, pain, fatigue, anxiety, depression, and global health does not typically result in increased distress in the participant, emotional distress or anxiety is a potential risk. We have used all of the proposed measures in our previous studies without any untoward effects. It is likely that some child and/or parents may experience some mild anxiety or discomfort related to completing the questionnaires; in rare cases a child or parent may experience substantial stress or discomfort. The likelihood of substantial stress or discomfort upon completing questionnaires is extremely low however in the event of this rare occurrence the PI would refer the child and/or parent to their legal medical provider, provide crisis line information, and provide a list of community counseling resources. In

addition, participants will be informed of their right to refuse to participate in any part of the data collection and will be given the phone numbers of the PI as well as the UW Institutional Review Board in the event that they desire further information or would like to issue a formal complaint. In our prior trials we have had no incidents and have successfully followed this monitoring protocol.

In addition, participants will be informed of their right to refuse to participate in any part of the data collection and will be given the phone numbers of the Principal Investigator as well as the UW Institutional Review Board in the event that they desire further information or would like to issue a formal complaint.

**Suicidal Ideation Assessment** Plan. In the event that one of the procedures reveals indicators of suicidal ideation, a standard suicide-risk plan will be implemented. Specifically, if any child comments about suicide in response to screening, assessments, or volunteers information about suicide or another crisis spontaneously in their online communications, staff will follow a flow chart that requires phone contact (not email) with the participant to complete several screening measures (Suicide Ideation Scale, Suicide Intent Scale) to assess risk. Staff will notify the PI and or Co-I in real-time. The PI who is a nurse (or a designated covering investigator such as Dr. Palermo, Co-I and licensed psychologist familiar with this protocol & has used this protocol successfully in her prior studies.) will be available 24 hours a day to be called via cell phone to address crisis questions. Psychiatric or other life crises that are high risk and imminent will be acted upon immediately with staff linking participants to appropriate crisis services. These are reviewed immediately with the clinically responsible PI and/or co-Investigator. Lower risk and less imminent crises are reviewed within 24 hours by the clinically responsible PI and/or co-Investigator. All actions taken will be documented on a case report form.

**Skin irritation**. The participant may experience mild skin irritation from wearing a watch device on their wrist. Child will have the option of wearing the Actiwatch over a long sleeve shirt to prevent skin irritation. If the participant cannot tolerate the watch, the participant may remove the watch. In our prior studies, none of the participants experienced skin irritation or intolerance of the Actiwatch.

**Confidentiality**. We have several safeguards planned to protect against the loss of confidentiality. All data will be coded with a study specific identifying number and all data (quantitative and qualitative) will be de-identified. The identifying number will be kept on a password-protected, secure server through the Information Technology (IT) department at the SON. The majority of data will be collected electronically via the REDCap system and minimal data (screening) will be obtained on paper. Participants' contact information will also be stored separate from study data and identifying numbers in a file on a password-protected server. All electronic data will be stored on password-protected servers. The wrist watch device will not contain any private or confidential information and will be linked to the participant only through the unique study identification number. Information will be compiled from all the participants in the study and, when published, data will be reported in aggregate form. As a result of aggregation, no individual participants will be identifiable from the written materials.

The subject's identity as a participant in this study will remain confidential; the research records kept confidential; and protected health information safeguarded as required by the UW IRB and HIPAA regulations. The research staff and the UW IRB will be allowed to inspect the information collected from this study. Only study identification numbers will be used to identify participants on the web site. Participants will be given unique user logins and passwords to access the Internet program and will be asked not to share these with anyone else. The software will be hosted on a secure server which has extensive safeguards in place with two firewalls, the latest virus protection, and daily back up of data. All contact information and identifying data will be stored in a secure location within the PI's sleep lab. The subject codebook will be kept on a password protected server to which only study staff has access.

Only the research staff and the UW IRB will be allowed to inspect the information collected from this study.

**Web-based Security**. Use of Secure Hyper Text Transmission Protocol (HTTPS) will provide an encrypted communication channel for all communications between the subject and the study staff, thereby minimizing the likelihood of interception or modification of data. Specifically, the encrypted connections will be used between the subject and the UW server where the data are housed, and between the study staff and the UW server. The system will identify individuals responsible for input by maintaining an audit trail associated with any creation, modification, or deletion of data. The audit trail will also require an explanation of why the data were changed, deleted, or added. The security of the UW web database servers, which only allow secure and restricted access to authorized individuals and is maintained by the UW Information Technology Group, makes the theft, alteration, or access of data extremely unlikely. As data accumulate in the relational database on the database server, it becomes increasingly important that the data be protected from theft, alteration, or unauthorized access of any kind. The database will reside on a server that is not used as a web server; therefore that server will be secured from HTTP, FTP and other forms of remote access. Placement of the database on a distinct, secure server will minimize the likelihood of theft or other malicious attacks. These security procedures will ensure that access to the server and the database is minimized and tightly controlled. An audit trail, with required explanation for any validating, editing, modification, or deletion of data will also be required at the database level.

**10.2 Reproductive risks**. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

*Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.*

[x] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

**a. Risks**. Describe the magnitude, probability, duration and/or reversibility of the risks.

**b. Steps to minimize risk**. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

*Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.*

*If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.*

**c. Pregnancy**. Describe what you will do if a subject (or a subject's partner) becomes pregnant

*For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?*

**10.3 Unforeseeable risks**. Are there any research procedures that may have risks that are currently unforeseeable?

*Example: using a drug that hasn't been used before in this subject population.*

[x] **No**
[ ] **Yes** → If yes, identify the procedures.

**10.4 Subjects who will be under regional or general anesthesiology.** Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[x] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

**10.5 Data and Safety Monitoring**. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

See DSMP—approved by NINR (see supplement materials).

**10.6 Un-blinding.** If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

**10.7 Withdrawal of participants.** If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Participants may withdraw from the study at any time. Participants will also be asked to provide rationale behind their decision to withdraw, though they may choose not to provide rationale. A member of the team will ask if the participants are willing to continue with follow-up assessments, participants may choose to participate in data collection or not.

In the event that one of the procedures reveals indicators of suicidal ideation (e.g., talking about suicide, forming a plan for suicide attempt) a standard suicide-risk plan will be implemented.

**10.8 Anticipated direct benefits to participants**. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

*Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.*

Benefits to participants include learning about their sleep patterns and strategies that may improve sleep self-management.

**10.9 Individual subjects findings.**

**a**. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

[ ] **No**
[X] **Yes** → If yes, explain whether and how you would share the information with the subject.

In the event participants screen positive for a sleep disorder and/or clinical depression and anxiety, we will inform participants and recommend an appointment with their primary care provider and we will also provide referral information.

**b**. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

[ ] **No**
[x] **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

**10.10 Commercial products or patents**. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

N/A

## 11 ECONOMIC BURDEN TO PARTICIPANTS

**11.1 Financial responsibility for research-related injuries.** Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

**11.2 Costs to subjects**. Describe any research-related costs for which subjects may be responsible (e.g., CT scan required for research eligibility screening; co-pays; cost of a device; travel and parking expenses that will not be reimbursed).

Participants will not have research-related costs.

**11.3 Reimbursement for costs.** Describe any costs to subjects that will be reimbursed (such as travel expenses).

Participants will not be reimbursed for travel because we do not require travel in this study.

## 12 RESOURCES

**12.1 Faculty Advisor.** (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

Advisor's name

Your relationship with your advisor (for example: graduate advisor; course instructor)

Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

**12.2 Study team communication**. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The study team has collaborated together on prior studies and are familiar with UW and SCH IRB policies, trained and certified in IRB, coercion, HIPAA, risk and benefits. The PI will provide the CRA and research team members at SCH with the approved consent forms and surveys prior to the start of the study. Procedure manuals will be used and checklists for data collection sessions. Any research assistants will be trained by the PI and monitored for adherence to procedures. If modifications are needed, the PI will use the same procedure. Further the study team will meet on a bi-weekly basis to discuss study procedures, recruitment, and challenges.

## 13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

**13.1 Other regulatory approvals**. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

*Do not attach the approvals unless requested by the IRB.*

| Approval | Research for which this is required |
|---|---|
| ☐ Radiation Safety | Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***. |
| ☐ Institutional Biosafety | Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA. |
| ☐ RDRC | Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes). |
| ☐ ESCRO | Procedures involving the use of some types of human embryonic stem cells. |

**13.2 Approvals and permissions.** Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

*Do not attach the approvals and permissions unless requested by the IRB.*

SCH Rheumatology clinic

**13.3 Financial Conflict of Interest.** Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.

## RESEARCH STRATEGY

### SIGNIFICANCE

**JIA and Sleep Deficiency.** JIA is the most common pediatric inflammatory disease with no known cure. An estimated 350,000 children in the U.S. are diagnosed with JIA; 20% of those experience lifelong pain and long-term disability.[12] JIA occurs throughout childhood with peak onset between 7 to 12 years.[13] Sleep deficiency, defined as a deficit in the quantity or quality of sleep obtained [14] is comorbid in JIA, affecting 20-30% of children.[1-4] Our previous findings show that 20% of 9-to-11 year-old JIA children slept 7.5 hours (below the 9 hour recommendation), and had poor quality sleep that was associated with increased fatigue and poorer HRQoL, regardless of active/inactive disease, disease duration, and pain.[1] Comorbid sleep deficiency with JIA may further exacerbate disease-related symptoms, and increase healthcare costs.

**Sleep Assessments in Pediatric Rheumatology Care.** In our prior study[1], 20% of the 9-11 year-old JIA children had sleep deficiency, yet none of these children had been screened for sleep deficiency, likely because the co-morbidity is often overlooked in clinical care. Pediatric providers have limited knowledge and skills to manage sleep deficiency in children,[15-17]despite it being highly comorbid in JIA. Low provider reimbursement rates, and high caseloads are barriers to assessing and treating sleep deficiency in pediatric care.[15-17]

**Conceptual Framework.** Our research was informed by the "impaired sleep" framework.[18] The self-management intervention for sleep deficiency (**SMID**) intervention targets self-management behaviors (patient activation, motivation, self-efficacy), expected to lead to better engagement in learning specific sleep strategies to increase sleep duration and improve health outcomes (**Fig. 1**). Self-management is an ongoing process of self-identifying needs and wants that require continual self-monitoring, problem solving, and the taking of appropriate actions.[19,20] *Self-efficacy* (belief in one's capabilities to organize and execute a course of action required to produce given goal)[21,22] is central to understanding changes in individuals' attainment in health status due to participation in self-management intervention programs. Individuals also need to be *motivated* and to become *actively engaged* in behavioral change. Because of the important role of parents in children's JIA management, self-management also includes parent's support of their child's treatment goals.

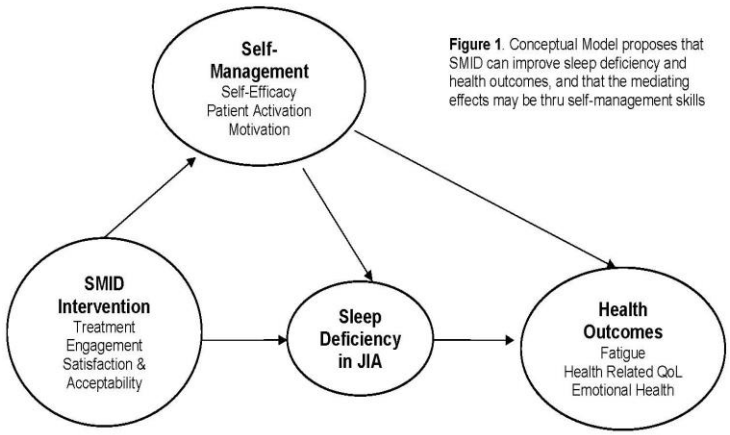



**Figure 1**. Conceptual Model proposes that SMID can improve sleep deficiency and health outcomes, and that the mediating effects may be thru self-management skills

**Self-management interventions for JIA**. Inadequate amounts of sleep and poor quality are modifiable behaviors. **Technology-based interventions that integrate self-management skills to promote healthy sleep in JIA do not exist**. Thus, treatment of sleep will remain suboptimal in a population at risk for sleep deficiency. Many of the existing sleep apps have been primarily tested in adults but are not developmentally appropriate for children,[23,24] do not include self-management components, have not been validated against actigraphy,[25-27] and target parents of young children.[28,29] Sleep deficiency in JIA is likely multifactorial, including pre-bedtime activities (homework, media), inconsistent sleep habits (bedtime variability), and/or a lack of necessary skills and self-efficacy to follow through with recommendations. An intervention that can modify *negative beliefs* ("My child will sleep better if I let him watch TV"), and *increase outcome expectations* ("Better sleep could make a big difference in my child's health") serves to *motivate* children and parents to make behavioral changes. Likewise, an intervention that promotes *self-efficacy* ("I can be patient and consistent in responding when my child wants to use media before bed") and facilitate changes in the social ("I can get my child on board with this plan") and physical ("I can remove the TV from my child's bedroom") environments can empower parents and children to follow through with behavioral changes. Lastly, an intervention that encourages *child/parent activation* ("My child and I can monitor progress, set new goals, and seek out the support we need") can give children and parents the tools to ensure their continued success. The proposed SMID intervention will be specifically designed to improve child sleep by modifying child/parent negative beliefs, increasing outcome expectations and self-efficacy, facilitating change in the social and physical environments, and encouraging child/parent activation.

**Scientific Premise**. Sleep deficiency is highly comorbid in JIA. Lack of sleep self-management interventions is an important problem because these children are vulnerable to the long-term consequences of poor sleep. Self-management interventions to promote healthy sleep do not exist, leaving a critical gap in care for this

population. Based on the success of self-management programs in other chronic illness populations, we expect that similar approaches to implementing a sleep self-management intervention in JIA will also be feasible and effective.

**INNOVATION.** Parents and children routinely use technology as a source of health information. Most children and parents do not have access to sleep self-management interventions in their communities. Access to Web-based technologies among youth is high [30,31] making the proposed intervention have extended reach and potential impact. The intervention itself is innovative in several ways, including the focus on the parent-child dyad, which offers an important opportunity to explore co-participation, and its emphasis on building self-management skills to effect changes in sleep health. The school-age years are an important age for healthy sleep habits and learning self-management skills[32-34] under parental supervision that contribute to improved health outcomes. This proposal builds on our prior collaborations with the *Center for Innovation* in Sleep Self-Management (Drs. Ward [Co-Director], Demiris [Core Director], Palermo [Advisory board]).

**PRELIMINARY DATA.** The team has extensive experience in JIA, sleep, use of actigraphy, development and testing of Web-based interventions, usability science, and intervention research in children and families.

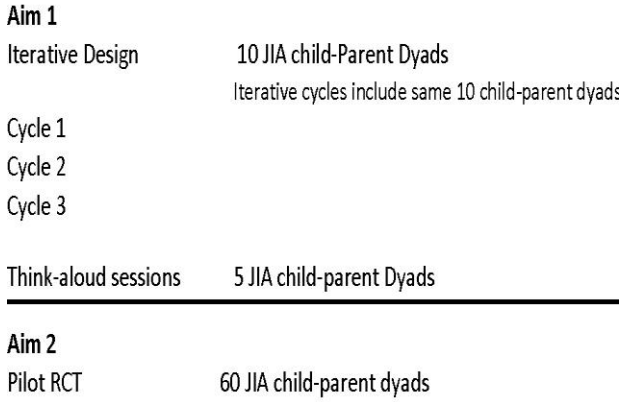
**Sleep Deficiency in JIA.** Our prior work shows that 40% of JIA children have sleep deficiency as measured by actigraphy, with an average duration of 7.5 hours and poor sleep quality (< 85%).[1,2] Sleep deficiency was associated with fatigue and increased anxiety.[35] *None* of the children had been previously screened or assessed for sleep deficiency.

**Evaluation of Web-Based Management of Adolescent Pain (WebMAP)**. Dr. Palermo (Co-I) has successfully conducted a series of RCTs with an internet delivered cognitive-behavioral self-management program (WebMAP) for chronic pain.[7,9,36-39] WebMAP components were based on evidence-based practices that incorporated strategies such as pain coping skills training, parent operant strategies, and relaxation training. The RCT involved 273 adolescents with chronic pain and their parents recruited from 14 pain centers in the U.S. and Canada.[7] Adolescents were randomized to one of two Internet treatment conditions, WebMAP (CBT pain intervention) vs WebED (education control). Adolescents receiving WebMAP achieved greater improvements on disability, pain-related anxiety, and parent behavior, and distress at 6-month follow up compared to adolescents receiving Internet Education. This experience in designing and delivering effective web-based self-management skills will help guide the approach of the proposed SMID.

## APPROACH

**Methodology.** There is a growing body of literature on the importance of usability testing for smartphone and web-based health programs.[40-44] Usability methodologies incorporate an iterative process of testing and refining the prototype to address user needs.[41] A qualitative approach using semi-structured, audio-taped interviews and user observation will be undertaken with iterative cycles of children with JIA and their parents to determine usability of the *SMID* user interface and to further refine the prototype.[40-44] This iterative rapid design development approach will concentrate on user performance (ease of use and learning, errors, and efficiency) and satisfaction with program content and functionality (reports, goal-setting). Based on recommendations[45] and previous team experience, each usability cycle will include 10 end-users. It typically takes 2-3 cycles to identify and resolve usability issues.[45] While human computer interaction literature recommends 5 users for a usability cycle, we aim for 10 end-users in each cycle to capture the potential breadth of user experiences and levels of familiarity with technology use (**Fig 2**).[46,47]

**Fig 2**: Study participation in the qualitative aspects of the study (including design, assessing usability and acceptance).




Participants. A sample of 15 children, 9-11 years with JIA, and parent (Aim 1, **Fig 2**) will be recruited from the Rheumatology clinic at Seattle Children's Hospital (SCH, **LOS Ringold**). In Washington State, over 6,100 children have been diagnosed with JIA.[48] Approximately 500 patients with JIA are seen each year in the Department of Rheumatology, and 250 are between 9 to 11 years.

Inclusion criterion for children: 1) diagnosed with JIA; 2) 9-11 years; 3) able to read/speak English; and 4) a score ≥ 41 on the Child Sleep Habits Questionnaire (CSHQ), suggestive of poor sleep.[1-3,49] This age group was chosen because of the developmental and physiological sleep needs are similar among children. Nine years of age was selected as the lower cut-off due to difficulty in reliably obtaining self-management measures with

children ≤ 8 years.[32-34] Exclusion criteria for children: 1) diagnosed sleep disorder (obstructive sleep apnea); 2) positive screen on the Pediatric Sleep Questionnaire for OSA[50](we will suggest follow up with the child's primary care provider because treatment of this condition is beyond the scope this intervention); 3) co-morbid conditions (e.g., ADHD, depression); 4) lack of daily access to the Internet or mobile device as the study will be conducted online. Parent is defined as the child's primary caregiver who co-resides with the child > 50% of the time. Inclusion criteria for parents: 1) > 18 years; 2) able to read/speak English. Exclusion criteria for parents: 1) working nightshift; 2) diagnosed with a chronic illness that would interfere with ability to complete study procedures;3) lack of daily access to the Internet or mobile device. If families have more than one eligible child, the child with the higher CSHQ score will be included. For families in which the child routinely spends the night in more than one home, a primary study parent will be identified and asked to complete all assessments.

**Aim 1. Apply a user-centered design approach to develop and refine a technology-based sleep self-management intervention (SMID).** We will use direct stakeholder input from children and parents about their needs for sleep self-management as well as intervention material from our prior Web-based interventions for youth with chronic pain that includes sleep hygiene education and a self-management focus to develop content for the SMID. We will use qualitative methods (iterative cycles of semi-structured audiotaped sessions with 10 children and parents and think-aloud observation sessions by a trained observer) to evaluate the usability of the SMID prototype. Results of these analyses will guide program finalization.

Content development team will involve PI (Ward), Co-I's (Palermo, Demiris),[11] and 3 pediatric behavioral sleep experts who are familiar in treating sleep deficiency. Palermo's existing WebMAP program for youth with chronic pain will guide the overall structure of the program and use of multimedia elements.[7] Content will be developed to address core components for treating sleep deficiency in children including sleep education, sleep skills training (consistent sleep schedule, bedtime routine), lifestyle changes (activities prior to bed), relaxation techniques, positive coping skills, communication) and parents (reinforce and modeling of positive coping skills, reward systems for activity participation, communication with children).[7] The content team will meet on a weekly basis to review content. After the team agrees on the content, multimedia elements, and structure of the program, the content will be integrated into an online format. The team will review and provide feedback, and modifications to the webpage prototypes will be incorporated.

Given the diverse platforms utilized currently (ranging from desktop to mobile devices) we will ensure that the system will be accessible not just for devices with keyboards and mouse, but also for smartphones and tablets. We will follow principles of "responsive web design" namely, a design solution that is adjustable to a variety of browser specifications and screen resolutions. This approach takes into account several factors such as user behavior, screen size, and operating platform. Responsive design responds automatically and optimally to the preferences of the user, regardless of their screen, hardware or browser software of choice.

In order to reflect user needs into the design, we will use an iterative approach with rounds of interview sessions with 10 dyads of children and parents per cycle for up to 3 cycles (**Fig 2**). Each interview session will be a one-hour semi-structured interview. During this interview the trained RA will solicit overall impressions about the design of the interface, perceived strengths and weaknesses of the approach as well as any suggestions for improving the content or functionality of the system. Following each cycle, changes will be made to the user interface based on problems and preferences identified during the previous cycle. The revised user interface will then be evaluated in a subsequent cycle (for a total of up to 3 cycles). The same participants will be recruited for each cycle.

Once the design has been finalized and the iterative design process has led to the finalized overall design approach, we will organize think-aloud sessions with 5 children-parent dyads (new participants; not previously involved in the iterative design process) to identify any potential usability issues (during months 8 and 9) and identify opportunities for improvement at a more granular level. We will use a mobile usability laboratory, including an electronic tablet loaded with the web application, data for 2 simulated dyads for testing, Morae recorder software (version 3.3). Co-I (Demiris) and RA will directly observe (and audio-record) 10 users individually (5 children and 5 parents) as they interact with the system. In addition, each user will be asked to "think aloud" about how they make specific choices in their interactions, talk through their engagement with the tools, verbally describe their actions and strategies when interacting with the tools, any suggestions, what they like or dislike, and whether or not navigation is intuitive.[51,52] As Nielsen points out,[53] running more test subjects increases the number of problems found but with progressively diminishing returns; since five test subjects will lead to identifying 77-85% of usability problems, it is recommend to engage 5 test users for think aloud sessions (in our case as we recruit dyads, we will have 5 children and 5 parents in the think-aloud sessions). A think-aloud protocol is based on the concept of participants being asked to think aloud as they interact with the

system and perform a set of specified tasks. Participants are asked to say whatever comes into their mind as they complete the task.[54] This might include what they are looking at, thinking, doing, and feeling. We will identify a series of tasks (such as setting goals, accessing graphs and educational resources) and ask participants to verbalize their thoughts as they try to complete these tasks. This provides insight into the participant's cognitive processes (rather than only their final impression), making thought processes as explicit as possible during task performance.[55] All verbalizations during these session will be transcribed and then analyzed.

**Data Analysis**. Quantitative data from the *Usability Error and Efficiency Documentation Form* will be analyzed using SAS 9.3. using descriptive statistics. Descriptive statistics will be calculated for quantitative usability measures (i.e., response time and accuracy) for specific tasks. Incomplete tasks or tasks that take longer than planned, will indicate a need for design improvements based on user feedback. Audio-recordings will be transcribed and then analyzed by members of the research team. Following procedures explicated by Braun and Clarke,[56] researchers will employ thematic analysis techniques to identify, analyze, and report patterns in the data. First, they will review all transcribed data, creating memos describing their initial impressions and noting areas for additional exploration. Then, they will meet to generate an initial list of codes. Over a series of face-to-face meetings, they will use NVivo 11 qualitative data management software to code the data with existing, refined, or newly created codes. Approximately halfway through qualitative data collection, researchers will begin sorting coded data into broader themes. Finally, researchers will define and name each theme, highlighting relationships among themes. Disagreements about themes will be handled through analyst consensus. Identified glitches, feedback, recommendations will be synthesized for programmers.

**Aim 2. Determine feasibility and initial efficacy of the SMID with children with JIA in a pilot RCT. We will determine study accrual and dropout rates as well as levels of patient acceptability and engagement in a pilot randomized controlled trial (RCT) comparing usual care to SMID intervention.** Preliminary effect sizes of the SMID will be determined in youth receiving treatment compared to usual care on primary outcomes of actigraphy sleep duration, sleep quality, and feasibility/acceptability, and secondary outcomes of child and parent self-management (activation, motivation, self-efficacy), technology use, recommendations for innovative sleep monitoring. We hypothesize that children who receive technology-based SMID vs. those who receive Usual Care will achieve increased sleep duration and efficiency (quality), immediately post-treatment and at 3 month follow-up.

Sample. Sixty children, 9-11 years, diagnosed with JIA and one parent will be recruited from the Pediatric Rheumatology Clinic at SCH and remotely via a flyer on the JIA foundation website.

Recruitment. At SCH, the clinical research assistant (CRA) will give eligible JIA families a study information flyer; the flyer will also be posted on the WA JIA website. For both SCH and the JIA website, interested families will contact the CRA by calling a phone number on the study flyer. The CRA will describe the study and screen for participation. Interested participants will be sent a consent/assent forms by mail, with a prepaid envelope. The recruitment methods were fruitful in our prior studies. Inclusion and exclusion criteria for JIA children and parents is above. Gender/minority inclusion: Girls and boys are eligible; we expect to enroll more Caucasian girls because the heightened disease prevalence among Caucasian girls and its relatively low prevalence in other ethnic groups.[57,58] JIA patients seen at SCH approximate the national ratio of female:male patients 4:1 and 95% Caucasian. Biologic variables: We will include sex as covariate in the statistical analysis due to the potential confounding effect on sleep.

Measures. **Table 2** shows the measurement plan for the study assessments.[2-27,59-72]

Power. We will enroll 60 dyads for a projected sample size of 50 (25/group), assuming 15% attrition. This meets recommendations for pilot trials[73] and provides 80-90% power to detect moderate effects based on a RM ANOVA model with three repeated measures and a correlation of 0.3 between the measurements. This power calculation was based on the moderate to large effect sizes for our outcomes of interest (total sleep time, d=.48; health related quality of life, d=.51; and fatigue, d = .79) found in our previous research.

Intervention. All JIA children and parents will receive access to the SMID program, which consists of two separate, password-protected web programs, one for child access and one for parent access. The intervention is completed in an 8-week period. The program design and treatment content of SMID follow cognitive behavioral, social learning, and family systems frameworks. Given the important role of parents in children's self-management of sleep deficiency, parents are engaged throughout the intervention period in their own treatment content intended to support their child's goals and to learn strategies to modify their own behavior in response to their child's sleep deficiency. The child modules will include: sleep education, sleep skills training

(e.g., daily record of activities before bed, sleep routine and schedule), lifestyle changes, relaxation techniques positive coping, relapse prevention, reward systems for activity participation. The parent modules include: sleep education, use of attention and praise to increase positive coping, strategies to support self-management skills and goals, modeling and communication. The program is designed to enhance self-management of sleep. Children set structured and personalized goals aimed at improving their self-management skills and sleep. Given the importance of homework and practice to change behavior, several components (e.g., positive feedback loops) actively encourage user attention and motivation in order to promote skills acquisition and rehearsal. The intervention will be interactive and personalized with tailored feedback. Using a diary function on the web site, children track their sleep in real-time and can generate customized reports and graphs from their data. Modules will take an estimated 20 minutes to complete and will include multimedia elements to enhance learning. Participants will be asked to spend additional time practicing skills and completing assignments at the end of each module. A message center will allow each child and/or parent to ask questions as they progress in the program. The PI will review messages, provide individualized feedback through Web message center. The web site uses a multimedia-rich format (e.g., animations, videos, audio clips) to deliver content. The website is built on a responsive platform and can be viewed on multiple devices (e.g., smartphones, laptops, tablets) to increase ease and flexibility of use. All app and website content is (a) written at a grade 4th grade reading level, (b) developmentally appropriate for 9-11 year-olds, and (c) is based on a unifying theme/narrative.

**Table 2: Measures**

| Concept | Measure: Target and Description including Duration and Frequency of Administration |
|---|---|
| **Sleep Deficiency** | |
| Inadequate Sleep | Actigraphy continuous recording of *child's* sleep-wake activity using (Actiwatch-L, MiniMitter-Respironics, Bend, OR).[25-27] Derived parameters: total sleep time, sleep efficiency, sleep onset (bedtime), sleep offset (wake time),wake after sleep onset; (T1,T2,T3)<br>Sleep Diary daily recording of *child's* pre-bedtime activities (media use, sports, caffeine intake), daily sleep (time to bed, sleep onset, # night awakenings); medications, & daytime activities (T1,T2,T3) |
| Sleep quality | Actigraphy & Sleep Diary-see above; (T1,T2,T3)<br>Child Sleep Wake Scale (CSWS)[59] 40-item *parent* report of sleep initiation during past month. Domains: going to bed, falling asleep, awakening, reinitiating sleep & wakefulness; yields total score; α=.89 (T1,T2,T3) |
| Sleep hygiene | Children's Sleep Hygiene Scale (CSHS)[60,61] 17 item *parent* report of activities around sleep during past month; sleep hygiene domains: pre-bedtime activities, bedtime routine, stable bedtime; yields total score; α=.78; (T1,T2,T3) |
| **Self-Management** | |
| NINR CDEs Self-efficacy | Self-Efficacy[62,63] 9-item *parent and child* report of their confidence in carrying out sleep-related behaviors (T1,T2,T3) |
| Motivation | Index of Self-Regulation (IRS)[64,65] 12-item *parent and child* report of motivation; subscales (recondition, stimulus control, behavioral monitoring); Established construct validity; IC reliability .72-.87 across different demographic groups and chronic illness conditions. (T1,T2,T3) |
| Activation | Patient Activation Measure[66]13-item *parent and child* report of knowledge, skill, & confidence for self-management; Adequate construct validity; IC reliability .81-.96; α=.91; demonstrated across age groups and different populations (T1,T2,T3) |
| **Daytime Function & Health Outcomes** | |
| Fatigue | Multidimensional Fatigue Scale[67] 18-item *child and parent-repor*t of fatigue in last month; yields 3 subscale (general fatigue, sleep/rest fatigue, cognitive fatigue) & total fatigue score. Reliability total α=.95, subscale .90-.93 (T1,T2,T3) |
| HRQoL<br><br><br>Emotional Health | PedsQL Generic Core Inventory[68,69] 23-item *child and parent-proxy* report of physical, social, emotional, school function; yields total score & 2 subscale scores (Physical & Psychosocial Health). Reliability total α >.88, subscales .80-.84. (T1,T2,T3)<br>PROMIS anxiety[70,71] 8-item *child* report of anxiety including fear, worry, hyperarousal (tension, nervousness) in the past week; Reliability .88 (T1,T2,T3) |
| **Descriptives** | |
| NINR Demographics | *Parent report* of demographics (parental age, education, race/ethnicity, child age, sex, race/ethnicity), medical and family history; Number of months since JIA diagnosis (T1) |
| Pain | Numeric Rating Scale (NRS)[72] *child* report of pain intensity with an 11-point NRS (0=no pain, 11=worse pain) (T1,T2,T3)-will be included in daily diary |

Measurement Plan. Assessment will occur at (T1 baseline), immediately after intervention (T2) and repeated at 3 months post-intervention (T3) for both the SMID and usual care groups. All questionnaires will be administered using REDCap, a secure web-based tracking and on-line data acquisition system. Children will wear an actigraph a reliable and validated measure of sleep[25-27] on their non-dominant wrist for 10 consecutive days, and complete an electronic symptom diary. After 10 days, parents will mail back the actiwatches in a prepaid self-addressed envelope used in PIs prior sleep studies.[1,27,35] Actigraphy data will be downloaded, scored, and a member of the team will follow up with parents to discuss the baseline sleep patterns within 1 week. Estimated time burden is 20 minutes for children and 10 minutes for parents. Response burden is minimized by online administration, which saves and stores responses.

Perceived usefulness and acceptance. About one third of all participants (33%; 20 out of 60 dyads) will be interviewed at study exit to assess their overall perceptions of the web-based program, the perceived usefulness and ease of use. All interviews will be conducted by trained RA in person or via telephone and will

be digitally audio-recorded. Specifically, questions will address the perceived impact of the system on sleep self-management, barriers and facilitators to use and whether children and parents would foresee future use and recommend the system to others. Audio-recordings will be transcribed and then analyzed by members of the research team. Following procedures explicated by Braun and Clarke,[56] described above.

Randomization. Following completion of baseline assessments, participants will be randomized to one of two treatment arms. Across groups, children will continue to receive their usual specialty medical care for JIA. A blocked randomization scheme will be generated using an online program to derive randomization assignment, programmed in the Internet sleep intervention, and not accessible to study investigators. Enrolled participants will be continuously randomized.

Usual Care. This treatment arm will receive usual JIA care, including annual Rheumatology clinic visits, medications, routine clinical and laboratory tests, physical therapy, follow-up appointments. Sleep intervention is not a part of usual care. The CRA will routinely review medical records and document any changes in medical care received during the intervention period.

**Data Analysis Plan**. Descriptive summaries of recruitment outcomes (number of contacts made related to interest in the study, numbers screened, eligible, enrolled, completed), and retention (number of parents and children who completed the study, dropouts, reasons given, timing of withdrawals) will be reported. Treatment engagement will be measured by completion of at least one module in the SMID program while adherence is defined as the completion of 5 or more modules. The administrative interface of the SMID program will have a tracking system in place for recording each time a user logs onto the web program. Overall usage statistics will include monitoring of program usage (number of logins, duration of time spent completing, time spent on a page or feature). Each module will contain multiple-choice quizzes concerning the content presented as well as behavioral assignments, fill-in-the-blank fields, and use of the diary tracker. All data fields that are completed within modules are stored, generating a comprehensive activity record of module specific use including self-management tasks. Exit interviews will be assessed as described above.

Data will be reviewed for completeness and errors including consistency checks for relevant variables. Tabular and graphical methods of data exploration including frequency tables and scatterplots will be used to explore distributions of study variables. We will adjust for sex, and considered use of either RM ANCOVA or generalized estimating equations (GEE) to evaluate intervention effects. We prefer GEE since it allows us to account for clustering of repeated assessments within individuals as well as the longitudinal nature of the data and provides higher power. Missing data will be examined for patterns and we will employ GEE multiple imputation to carry out ITT analysis. Single degree of freedom contrasts by group will be examined if there are significant changes in sleep measures from pre- to post-treatment and/or from pre- to 3-month follow-up for SMID vs Usual Care. Secondary treatment outcomes will be examined using GEE to explore for mean changes across time and between groups using interaction terms and contrasts. The range of outcome measures will allow us to obtain experience with alternative measures of sleep, self-management measures that will inform our future research. Outcome data will also be used to generate effect size point estimates for the future large-scale trial. **Design Considerations, Alternative Strategies and Timeline**. Project constraints on research time and resources will pose study limitations, which we have adjusted for in the study design and timeline. As the study requires participant enrollment for 5 months, we anticipate some challenges around retention, and have addressed this with a number of strategies described below. Co-I, Dr. Palermo successfully recruited and retained youth with chronic pain in Web-based interventions over a period of 12 months (>90% retention). An attention control group and other parent/child variables were considered but feasibility, acceptability, and proof of concept were prioritized for this initial phase. **Rigor and Transparency** will be ensured by: 1) the proposed methods (usability, expert panel, parent/child input); 2) use of successful retention strategies from prior studies; 3) documentation of attrition; 4) sample size derived from a priori power analysis; 5) statistical methods to account missing data and change overtime. **Retention**. We will make every effort to retain participants with fruitful methods used in our prior studies including: 1) automated reminders built into the Web program; 2) phone calls scheduled at convenient times, 3) incentives for completion of each assessment ($20 gift card/each Aim 1; Aim 2 [ T1 $40 gift card each; T2 $60 gift card each; T3 $80 gift card each]), 3) semi-structured interviews *prior to* intervention development; and 4) exit interviews post-intervention. **Strengths** include: 1) successful recruitment of JIA children; 2) expertise in sleep, technology-based interventions, usability assessments; 3) leveraging of successful methods in a prior Web-based interface; 4) development of the first low resource demand, convenient, and personalized sleep self-management intervention for JIA. Findings generated will address important methodological issues needed to develop innovative sleep self-management intervention for children with chronic illnesses and their parents.