Feasibility of a Sleep Intervention for Children with Autism Spectrum Disorder Study

NCT04452045

October 5, 2021

Study Application (Version 1.7)

1.0 General Information

***Enter the full title of your study:**

Feasibility of a Sleep Intervention for Children with Autism Spectrum Disorder

***Enter the study alias:**

RAS # A127552
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add departments

2.1 and Specify Research Location:

Is Primary?	Department Name
ⓘ	**UCSF** - *133100* - M_Psychiatry

3.0 List the key study personnel: (Note: external and affiliated collaborators who are not in the UCSF directory can be identified later in the Qualifications of Key Study Personnel section at the end of the form)

3.1 *Please add a Principal Investigator for the study:

Asarnow, Lauren D PhD

Select if applicable

☐ Department Chair ☐ Resident

☐ Fellow

If the Principal Investigator is a Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel

A) Additional Investigators

Bush, Nicole PhD
Other Investigator
Leventhal, Bennett MD
Other Investigator

B) Research Support Staff

Mirchandaney, Riya
Study Coordinator

3.3 *Please add a Study Contact

Asarnow, Lauren D PhD
Mirchandaney, Riya

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor/Mentor:

Leventhal, Bennett MD

3.5 If applicable, please select the Designated Department Approval(s)

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

4.0 Initial Screening Questions

Updated April 2020 - Revised Common Rule (January 2018) Compliant / COVID-19 - v94

4.1 * PROJECT SUMMARY: (REQUIRED) Give a brief overview of this project (250 words or less). Tell us what this study is about, who is being studied, and what it aims to achieve. If you have an NIH Abstract, paste it here (Click on the orange question mark to the right for more detailed instructions):

This proposal will acquire preliminary data on the feasibility and effectiveness of an innovative and scalable strategy for improving access to effective sleep health care for preschool-aged children with ASD. We will develop and test an adaptation of the existing behavioral sleep interventions for preschool aged children. This adaptation will address key challenges to sleep health care for children with ASD: (1) Learning differences of children with ASD by incorporating intervention principles from the TEACHH model; (2) Overcome the challenge of treatment access due to the limited number of qualified providers by developing didactic videos for online and mobile device delivery (referred to as SweetDreams); and, (3) SweetDreams will use a dynamic process involving extensive collaboration with children, parents, developmental pediatricians, and other experts on youth with ASD.

4.2 * HUD DEVICE: (REQUIRED) Does this application involve a Humanitarian Use Device (HUD):

- (●) No
- ( ) Yes, and it includes a research component
- ( ) Yes, and it involves clinical care ONLY

4.3 * TYPE OF RESEARCH: (REQUIRED) Select the option that best fits your project (Click the orange question mark to the right for definitions and guidance):

- ( ) Biomedical research (including medical records review, biospecimen collection and/or use, other healthcare or health outcomes related activities, research database, biospecimen bank, or recruitment registry)
- (●) Social, behavioral, educational, and/or public policy research
- ( ) Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at

biological measures)

4.4 * SUBJECT CONTACT: (REQUIRED) Does this study involve ANY contact or interactions with participants:

- (•) Yes (including phone, email or web contact)
- ( ) No (limited to medical records review, biological specimen analysis, and/or data analysis)

4.5 * RISK LEVEL: (REQUIRED) What is your estimation of the risk level, including all screening procedures and study activities:

- (•) Minimal risk
- ( ) Greater than minimal risk

4.6 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

- ( ) Full Committee
- (•) Expedited
- ( ) Exempt

4.7 * EXPEDITED REVIEW CATEGORIES: (REQUIRED) If you think this study qualifies for expedited review, select the regulatory categories that the research falls under: (check all that apply)

- [ ] Category 1: Research using approved drugs or devices being used for their approved indications
- [ ] Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
- [ ] Category 3: Prospective collection of biological specimens for research purposes by noninvasive means (e.g. buccal swabs, urine, hair and nail clippings, etc.)
- [ ] Category 4: Collection of data through noninvasive, routine clinical procedures (e.g. physical sensors such as pulse oximeters, MRI, EKG, EEG, ultrasound, moderate exercise testing, etc. - no sedation, general anesthesia, x-rays or microwaves)
- [ ] Category 5: Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for nonresearch purposes
- [x] Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes
- [x] Category 7: Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factorsevaluation, or quality assurance methodologies

4.9 * DATA/SPECIMEN ANALYSIS ONLY: (REQUIRED) Does this study ONLY involve records review and /or biospecimen analysis (do not check 'Yes' if this is a registry, research or recruitment database, or biospecimen repository):

( ) Yes (•) No

4.10 * CLINICAL TRIAL: (REQUIRED)
Is this a clinical trial:

According to The World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE) a clinical trial is:

- Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

ICMJE requires registration of a clinical trial in a public database (such as ClinicalTrials.gov) prior to enrollment, for eventual publication of results in member biomedical journals.
Guidance: Public Law 110-85 requires that all investigators who perform an *applicable clinical trial* must ensure that the trial is registered on a government web site called **ClinicalTrials.gov**.

The FDA requires registration for 'applicable clinical trials,' defined as follows:

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

For additional information on the **ClinicalTrials.gov** registration process at UCSF and the definition of a clinical trial for purposes of registration, visit the **ClinicalTrials.gov section of the UCSF Clinical Research Resource HUB**.

(•) Yes ( ) No

Clinical Trial Registration - 'NCT' number for this trial:

NCT04452045

4.11 * CLINICAL TRIAL PHASE: (REQUIRED) Check the applicable phase(s):

- [ ] Phase 0
- [x] Phase 1
- [ ] Phase 1/2
- [ ] Phase 2
- [ ] Phase 2/3
- [ ] Phase 3
- [ ] Phase 4
- [ ] Not Applicable

4.12 * INVESTIGATOR-INITIATED: (REQUIRED) Is this an investigator-initiated study:

(•) Yes ( ) No

The UCSF IRB recommends use of the Virtual Regulatory Binder to manage your study.

4.13 * CORONAVIRUS RESEARCH: (REQUIRED) Does this study involve research on coronaviruses (COVID-19, SARS, MERS or other):

○ Yes ◉ No

4.15 * CANCER: (REQUIRED) Does this study involve cancer (e.g., the study involves patients with cancer or at risk for cancer, including behavioral research, epidemiological research, public policy research, specimen analysis, and chart reviews):

○ Yes ◉ No

4.16 * RADIATION EXPOSURE: (REQUIRED) Does your protocol involve any radiation exposure to patients /subjects EITHER from standard care OR for research purposes (e.g., x-rays, CT-scans, DEXA, CT-guided biopsy, radiation therapy, or nuclear medicine including PET, MUGA or bone scans):

○ Yes ◉ No

4.17 SCIENTIFIC REVIEW: If this study has undergone scientific or scholarly review, please indicate which entity performed the review (check all that apply):

☐ Cancer Center Protocol Review Committee (PRC) (Full approval is required prior to final IRB approval for cancer-related protocols.)
☑ CTSI Clinical Research Services (CRS) Advisory Committee
☐ CTSI Consultation Services
☐ Departmental scientific review
☐ Other:

4.18 * STEM CELLS: (REQUIRED) Does this study involve human stem cells (including iPS cells and adult stem cells), gametes or embryos:

◉ No
○ Yes, and requires IRB and GESCR review
○ Yes, and requires GESCR review, but NOT IRB review

4.19 * FINANCIAL INTERESTS: (REQUIRED) Do you or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study:

○ Yes ◉ No

5.0 Funding

5.1 * FEDERAL FUNDING: (REQUIRED) Is this study currently supported in whole or in part by Federal funding, *even by a subcontract*, OR has it received ANY Federal funding in the past:

◉ Yes ○ No

5.2 * DoD INVOLVEMENT: Is this project linked in any way to the Department of Defense (DoD): (REQUIRED)

○ Yes ◉ No

5.3 SPONSORS: Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor:

External Sponsors:

View Details	Sponsor Name	Sponsor Type	Awardee Institution:	Contract Type:	Project Number	UCSF RAS System Award Number ("A" + 6 digits)
⊟	NIH Natl Ctr Advancing Translational Sci	01	UCSF	Grant		

Sponsor Name:	NIH Natl Ctr Advancing Translational Sci
Sponsor Type:	01
Sponsor Role:	Funding
CFDA Number:	
Grant/Contract Number:	
Awardee Institution::	UCSF
Is Institution the Primary Grant Holder:	Yes
Contract Type:	Grant
Project Number:	
UCSF RAS System Award Number ("A" + 6 digits):	
Grant Number for Studies Not Funded thru UCSF:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	
Explain Any Significant Discrepancy:	

Other Funding Sources and Unfunded Research - Gift, Program, Departmental or other Internal Funding (check all that apply):

- ☐ Funded by gift (specify source below)
- ☑ Funded by UCSF or UC-wide program (specify source below)
- ☐ Specific departmental funding (specify source below)
- ☐ Unfunded (miscellaneous departmental funding)
- ☐ Unfunded student project

* Identify the gift, program, departmental, or other internal funding source: **(REQUIRED)**

NIH Natl Ctr Advancing Translational Sci

6.0 Sites, Programs, Resources, and External IRB Review

6.1 * UCSF AND AFFILIATED SITES (check all that apply): (REQUIRED)

- ☐ UCSF Benioff Children's Hospital Oakland (BCHO)
- ☐ UCSF Cancer Center Berkeley

- [ ] UCSF Cancer Center San Mateo
- [ ] UCSF China Basin clinics and facilities
- [ ] UCSF Helen Diller Family Comprehensive Cancer Center
- [x] UCSF Langley Porter Psychiatric Institute (LPPI)
- [ ] UCSF Medical Center at Mission Bay (Benioff Children's Hospital, the Betty Irene Moore Women's Hospital, Bakar Cancer Hospital, or outpatient clinics)
- [ ] UCSF Mount Zion
- [ ] UCSF Parnassus (Moffitt-Long hospital, dental clinics or other outpatient clinics)
- [ ] UCSF Other Sites (including Laurel Heights and all the other sites outside the main hospitals and clinics)
- [ ] Fresno - UCSF Fresno OR Community Medical Center (CMC)
- [ ] Gladstone Institutes
- [ ] Institute on Aging (IOA)
- [ ] Jewish Home
- [ ] SF Dept of Public Health (DPH)
- [ ] SF VA Medical Center (SF VAMC)
- [ ] Vitalant (formerly Blood Centers of the Pacific and Blood Systems Research Institute)
- [ ] Zuckerberg San Francisco General (ZSFG)

6.2 LOCATIONS: At what locations will study visits and activities occur:

At this time, all study visits will take place over Zoom.

6.3 OFF-SITE PROCEDURES: Will any study procedures or tests be conducted off-site by non-UCSF personnel:

- ○ Yes
- ◉ No

6.4 RESEARCH PROGRAMS: Check any UCSF research programs this study is associated with:

- [ ] Cancer Center
- [ ] Center for AIDS Prevention Sciences (CAPS)
- [ ] Global Health Sciences
- [ ] Immune Tolerance Network (ITN)
- [ ] Neurosciences Clinical Research Unit (NCRU)
- [ ] Osher Center
- [ ] Positive Health Program

6.5 * CTSI CRS SERVICES: (REQUIRED) Will this study be carried out at one of the UCSF Clinical Research Services (CRS) units or utilize CRS services:

- ○ Yes
- ◉ No

6.6 * MULTI-CENTER TRIAL: (REQUIRED) Is this a multi-center or multi-site research trial:

By '**multi-center trial**' we mean a study where the protocol is developed by an lead investigator, an industry sponsor, consortium, a disease-group, etc.,and multiple sites across the nation or in different countries participate in the trial. The local sites do not have any control over the design of the protocol.

- ○ Yes
- ◉ No

6.8 OTHER SITE TYPES: Check all the other types of sites not affiliated with UCSF with which you are cooperating or collaborating on this project:

Do NOT check any boxes below if this is a multi-center clinical trial, UCSF is just one of the sites, and neither UCSF nor one of its faculty-linked affiliates (SF VAMC, Gladstone, ZSFG) are the coordinating center.

- ☐ Other UC Campus
- ☐ Other institution
- ☐ Other community-based site
- ☐ Foreign Country
- ☐ Sovereign Native American nation (e.g. Navajo Nation, Oglala Sioux Tribe, Havasupai, etc.)

6.14 * RELYING ON AN EXTERNAL IRB: (REQUIRED) Does this application include a request to rely on an external IRB (a central IRB (other than the NCI CIRB) or an external IRB (other UC campus, commercial, or institutional):

○ Yes ◉ No

7.0 Research Plan and Procedures

7.1 HYPOTHESIS: Describe the hypothesis or what the study hopes to prove:

We hypothesize that the SweetDreams intervention will improve child sleep and behavior as well as the sleep and mental health of their caregivers.

7.2 AIMS: List the specific aims:

Aim 1a: In Phase I we will develop and assess the acceptability of the SweetDreams sleep intervention for youth with ASD, using existing, evidence-based behavioral sleep interventions for mobile device delivery.

Aim 1b: Use an iterative intervention development process to pre-test the intervention with 5 children and their parents to make sure that it is user-friendly, developmentally appropriate, engaging, and acceptable. After reviewing initial quantitative and qualitative data on usability, acceptability, and outcomes, we will refine the intervention and pre-test the refined intervention with 5 more children and their parents. This will be followed by a final set of revisions, as needed.

Aim 2: In Phase II we will conduct a pilot RCT in which 20 children (12-60 months) with ASD and sleep problems will be randomized to SweetDreams (n=10) or a wait-list control (n=10) to assess the effectiveness of SweetDreams. We hypothesize that SweetDreams will result in improved sleep behaviors as measured by the Children's Sleep Habits Questionnaire (H1a: Primary Outcome) and the Pittsburgh Sleep Quality Index for the caregivers (H1b; Secondary hypothesis), compared to wait-list control.

Aim 3: Explore the effects of SweetDreams on child behavior and caregiver mental health outcomes. We test the hypothesis that SweetDreams results in improvements in multiple domains of child behavior and caregiver mental health, using caregiver reports of child behavior and caregiver self-report measures, compared to the wait-list control condition.

7.3 DESIGN: Briefly describe the study design (e.g., observational, interventional, randomized, placebo-controlled, blinded, cross-over, cross-sectional, longitudinal, pharmacokinetic, etc.):

This treatment development trial will develop (Phase I) and evaluate the potential efficacy of SweetDreams in a pilot randomized controlled trial among parents of preschool aged children with ASD and a sleep problem (Phase II). Phase II will include a waitlist control group, which will be given access to SweetDreams following the post-treatment assessment.

7.4 BACKGROUND AND SIGNIFICANCE: Briefly provide the background and significance of this study (e.g. why is this study needed) (space limit: one half page):

Sleep problems are one of the most common concurrent clinical disorders among children with Autism Spectrum Disorder (ASD), with a prevalence ranging from 40% to 80% Based on parental reports, Krakowiak and colleagues found that 53% of children with ASD between the ages of 2 and 5 years had at least one sleep problem compared to 32% of typically developing children.

Peak onset of sleep problems among children with ASD is during the second year of life. Sleep problems often last for many years and sometimes continue into adulthood. In one study, over 50% of children with autism report at least one sleep problem, with a peak onset during the second year of life. In another study, 63% of children with ASD and sleep problems experienced persistence of sleep difficulties over time.

Sleep problems interfere with developmental progression and exacerbate problems in daily adaptive function for children with autism. Parents of poorly sleeping children with ASD routinely report worse daytime behavior following nights of fragmented or insufficient sleep. Studies have demonstrated that short sleep duration was associated with social skills deficits, stereotypic behavior, and increased overall autism scores.

Sleep problems are associated with higher ratings of caregiver stress. Sleep problems were reported by almost 70% of 210 Hong Kong families with a young child with ASD. Severity of sleep problems predicted parental stress in these children. Sleep maintenance difficulties in children with ASD have a significant impact on parental sleep. A recent study by Meltzer reported poorer sleep quality and shorter total sleep time among parents of children with autism compared to parents of typically developing children.

Behavioral sleep treatments are known to improve sleep among preschool aged children. Behavioral interventions like graduated extinction, scheduled nocturnal awakenings, and bedroom passes can be utilized to set appropriate behavioral limits at bedtime and to promote the development of more adaptive self-soothing skills. Sleep hygiene and behavioral therapy have demonstrated effectiveness of behavioral interventions for sleep onset and maintenance problems in children with ASD.

There are few providers with expertise in behavioral sleep treatments, which limits access to care, especially for children with ASD. There are only 412 registered providers for behavioral sleep interventions in the U.S. (for all ages). Very few of those providers are qualified to treat children, and even fewer have training working with children with ASD. The relatively large numbers of children with ASD and sleep problems cannot realistically be effectively treated using an in-person treatment model; thus, a new approach is needed that does not require direct access to highly trained providers.

mHealth interventions can address significant barriers to treatment access and have demonstrated effectiveness. Current barriers to receiving sleep/behavioral health care include limited availability of qualified providers, long wait time when providers are identified, geographically inconvenience, and necessity for missed work or school. An mHealth intervention for parents of children with ASD could help address these significant barriers. Moreover, there is evidence of effectiveness for parent targeted mHealth interventions for improving child sleep.

The Sleep Committee of the Autism Treatment Network (ATN) recently concluded that evidence-based standards for the behavioral, pharmacologic, and other treatments of insomnia in ASD are not yet available. *There are 2 primary reasons that existing sleep interventions need to be specially tailored for children with ASD.*

First, sleep problems among children with ASD are highly heterogenous. Sleep onset and maintenance problems resulting in reduced sleep duration are the most common concerns expressed by the parents of children with ASD. Circadian rhythm disturbances have also been reported in children with ASD, including irregular sleep–wake patterns, free running sleep/wake rhythms, sleep onset delay and early morning awakening have been reported in children with autism. The heterogeneity of sleep difficulties points to the necessity of developing a modularized treatment, as has been used previously.

Second, there is considerable heterogeneity in learning styles amongst individual with ASD, necessitating multiple and flexible approaches to behavioral treatment strategies. SweetDreams incorporates the evidence-based practices of TEACCH, including 1) the importance of clearly defined physical boundaries for spaces that serve difference purposes; 2) having a consistent schedule visualized through drawings and photographs; 3) routine is essential because the one of the most important functional support systems for autistic individuals is consistency; and, 4) visual structure involves visually-based cues for reminders and instruction.

7.5 PRELIMINARY STUDIES: Briefly summarize any preliminary studies relevant to your proposed research (space limit: one half page):

Utilizing the method proposed for the present project and described in phase 1, Dr. Asarnow developed BrightMobile, a mHealth adaptation of evidence-based sleep health interventions for teens. BrightMobile was developed and pre-tested within a one year period. BrightMobile is now being tested in a primary care practice that primarily serves MediCal patients. 22 youth (M age 15, 95% minority), recruited from primary care over a 6-month period, independently provided feedback on the BrightMobile video content and delivery. Quantitative prepost data indicate a significant improvement in both sleep quality and depression symptoms.

7.6 * TREATMENT PROTOCOL: Is this a treatment study, i.e. does this study intend to provide treatment to individuals with a medical or psychological condition: (REQUIRED)

(•) Yes ( ) No

7.7 * BILLABLE PROCEDURES: Does this study involve any procedures, lab tests or imaging studies that have a CPT code and could be billable to patients, their insurance, Medi-Cal, Medicare, or any other entity (answer 'Yes' even if the study is going to pay for all the procedures): (REQUIRED)

( ) Yes (•) No

If you are not sure if your study involves billable procedures, send an email to the UCSF Office of Clinical Research (OCR) for help answering this question.

7.8 * COMMON RESEARCH ACTIVITIES: Types of research activities that will be carried out. Check all that apply and describe in more detail in the 'Procedures / Methods' section: (REQUIRED)

- [x] Interviews, questionnaires, surveys
- [ ] Educational or cognitive tests
- [ ] Focus groups
- [ ] Social media-based research activities
- [ ] Observation
- [ ] Fitness tests or other exertion activities
- [x] Use of mobile health apps or other apps
- [ ] Collection of data from wearable tech such as Fitbit, Apple Watch, Garmin, motion actigraphs, etc.)
- [ ] Non-invasive imaging or testing (MRI, EEG, pulse oximetry, etc.)
- [ ] Imaging procedures or treatment procedures that involve radiation (x-rays, CT scans, CT-guided biopsies, DEXA scans, MUGA or PET scan)
- [ ] Administration of contrast agent
- [x] Randomization to one intervention versus another
- [x] Use of placebo
- [ ] Biopsy conducted solely for research purposes
- [ ] Sham surgical procedure
- [ ] None of the above

7.9 * PROCEDURES / METHODS: (REQUIRED)

Describe the research methods and study activities taking place at each site (e.g. what will participants be asked to do and what will members of the study team do?). If there will be multiple participant groups or study sites, explain what will happen with each group or study sites.

If some of the activities would occur even if the person were not in the study, as in the case of treatment or tests performed for diagnostic purposes, **clearly differentiate between those activities that will be done solely for research purposes and those that are happening as part of routine care.**

Please call our office at 415-476-1814 and ask to speak to someone on the Expedited Review team if you need help differentiating between what parts are research and what parts aren't.

To be included in the study, children must a) have poor sleep health defined by the Children's Sleep Habit Questionnaire (scoring 41 or higher); and, b) have a diagnosis of ASD. Exclusion criteria are: any regular sleep medication use (this does not include occasional over the counter sleep aid), known sleep apnea, unstable major medical conditions (e.g. severe asthma, diabetes).

Phase I begins with the development and refinement of SweetDreams. Phase I involves 2 distinct stages as described below and uses an iterative intervention development process (N=10).

1. Development of SweetDreams (months 1-3): Dr. Lauren Asarnow at UCSF will develop SweetDreams for the purpose of this research study, which will provide preliminary data for a larger scale effectiveness trial. SweetDreams. will adapt existing evidence based sleep interventions to address the most common sleep disturbances among children with ASD (difficulties initiating or maintaining sleep, circadian dysregulation, and bedtime resistance1) for a mobile health delivery platform. This phase features refining and adapting the SweetDreams manual into distinct learning modules. Learning modules are designed for parents and will feature interactive animated videos; these are elements that research indicates promotes utilization and retention of content learned. The team will work with an animator to develop the video content. The mobile delivery will be conducted via Twilio on REDCAP. Worksheets that help apply the didactic content from the videos to the child will also be delivered via REDCAP. We will receive no data from VImeo or Twilio: we will only receive a timestamp for when the participant opens the REDCap questionnaire containing the video and when they mark it as complete.
2. Pre-Test (months 3-8): We will pre-test the intervention with 5 children and their parents. Parents will be asked to participate in the intervention, which provides parents with behavioral skill training that they will ideally implement with their children every day, and they will be asked to complete post-treatment qualitative (interview) and quantitative (Credibility Expectancy Questionnaire; CEQ34) assessments regarding intervention usability, acceptability, and outcomes. Post-treatment qualitative interviews will be recorded. Audio files will be stored in an encrypted folder and transcribed after data collection is complete. Audio files will be destroyed upon completion of data analysis. No other assessments will take place in Phase I. The goals are to (1) streamline screening and recruitment materials; (2) use feedback to ensure SweetDreams is user friendly and developmentally appropriate; (3) solicit feedback from the participating parents to be reviewed with the research team (Drs. Asarnow, Bush and Leventhal). This process will involve extensive collaboration with parents. This approach is in line with the emphasis by NIH that collaboration can "develop more effective interventions…by targeting interventions to the identified needs of community members." Here, we anticipate two key benefits: the research team can learn from the parents about how their daily habits and experiences within their families affect their child's sleep. The intervention will be refined based on feedback from parents, that will then be reviewed by Drs. Asarnow, Bush and Leventhal. We will pre-test the refined intervention with 5 children and their parents. After review of new data, the intervention will be refined as needed. We expect this will be sufficient for Phase 1 intervention development, but will conduct additional piloting if needed.

Phase II consists of the pilot feasibility RCT. In the second phase (months 8–12) we will conduct a small pilot, randomized, controlled trial to establish the basis for proposing a larger scale

intervention study. The RCT will be conducted with children (aged 12-60 months) with ASD and sleep problems (N = 20) who will be randomized to one of two groups: (a) SweetDreams (n = 10) or (b) wait-list control (n = 10).

1. Recruitment and Screening: Children and their parent(s) will be recruited from the STAR Autism Clinic and the Division of Developmental Medicine. Eligible families will be given an information sheet describing the study when registering for their appointment. If families are interested in the study, they will be consented and asked to complete an initial screening measure. Families who screen positive for sleep problems will be scheduled for a telephone screening to determine if all eligibility criteria are met. Eligible participants will then be scheduled to complete a baseline assessment and randomization.
2. Baseline Assessment: Eligible children and their parents will attend a baseline assessment measure collection via telephone/Zoom. At the end of the baseline assessment, families will be randomized to either SweetDreams or the waitlist control condition. All assessment staff will be blind to treatment condition. If a family is randomized to receive the SweetDreams, a separate research assistant (RA) not involved in assessments will orient the parents to the treatment. The parent will complete the baseline learning modules of the program and be given an opportunity to set goals and ask any questions they have about the program.
3. Post-Treatment Assessments: Post-Treatment assessments will be conducted via telephone /Zoom. Following the Post-Treatment assessment, families who were in the wait-list control condition previously will be oriented to SweetDreams. The parent will complete the baseline learning modules of the program and be given an opportunity to set goals and ask any questions they have about the program. An additional Post-Treatment assessment will be conducted for wait-list control participants at the end of their treatment course. Apart from Screening, Baseline, and Post-Treatment Assessments, no other assessments will take place.

The SweetDreams Intervention will be structured as follows:

Four core modules will be delivered to all families in a prescribed order. The participants' responses to the CSHQ assessment at baseline will dictate which sleep problems they report and which optional modules will be assigned.

Baseline. Core Module. a) *Self-assessment, case formulation, and goal setting.* The frequency, intensity and duration of symptoms covering the periods before bed, during the night, shortly after waking and during the day. Goals are identified and operationalized. b) *Basic behaviorism.* R eview basic behavioral learning in order to promote behavioral change. Parents develop a menu of skills to extinguish and/or promote behaviors.

Week 1. Core Module. a) *Establishing bedtime and naptime routine.* Education about the importance of routine both for ASD and for building positive sleep associations.
Develop consistent schedule visualized through drawings and photographs. b) *Establishing Regular-Sleep Wake Schedules*. Discussion of basic sleep and circadian science and the importance of maintaining regularity in sleep schedule (including on weekends). Discuss common obstacles to adherence.

Week 2. Core Module. *Limit Setting & Positive Reinforcement.* We build the motivation for parents to begin to set limits around sleep. Review the importance of consistency and the power of positive reinforcement to create behavior change. Create a visual structure involving visually-based cues for reminders and instruction on set limits. Create clearly defined physical boundaries for sleep space.

Week 3. Optional Modules (families will get assigned modules a through d based on CSHQ assessment): a) *Calm Down Strategies.* Develop a list of strategies to help parents support their child to calm down when they get agitated or excited before bed or in the middle of the night. Emphasis is on developing self-soothing strategies for children. Strategies including breathing techniques, listening to an audiobook, bean bag press, or hugging a stuffed animal; b) *Managing Middle of the Night Awakenings*. Develops strategies for parents to manage children waking in the middle of the night; c) *Managing Early Morning Awakenings.* Develops strategies for parents to manage children's early morning awakenings. Discusses circadian cues that can be emphasized; and, d) *Managing Curtain Calls.* Develops strategies for parents to manage children who keep getting out of their bed after being put to bed.

Week 4. Core Module. *Relapse prevention.* The goal is to consolidate gains and prepare for setbacks.

7.10 STANDARD CLINICAL PRACTICE: To what extent, if any, do the planned research procedures differ

from the care that people would otherwise receive at this institution or the study site if not being done locally:

Behavioral interventions like graduated extinction, scheduled nocturnal awakenings, and bedroom passes can be utilized to set appropriate behavioral limits at bedtime and to promote the development of more adaptive self-soothing skills. Sleep hygiene and behavioral therapy have demonstrated effectiveness of behavioral interventions for sleep onset and maintenance problems in children with ASD. However, there are only 412 registered providers for behavioral sleep interventions in the U.S. (for all ages). Very few of those are qualified to treat children, and even fewer have training working with children with ASD. The relatively large numbers of children with ASD and sleep problems cannot realistically be effectively treated using an in-person treatment model; thus, a new approach is needed that does not require direct access to highly trained providers.

The Sleep Committee of the Autism Treatment Network (ATN) recently concluded that evidence-based standards for the behavioral, pharmacologic, and other treatments of insomnia in ASD are not yet available.

7.11 INSTRUMENTS: List all questionnaires, surveys, interview, or focus group guides that will be used for this study:

If the instruments are not complete or not available because they will be developed as part of this study, describe the basic content or include an outline and submit the final versions to the IRB with a modification for approval prior to use.

- Children's Sleep Habits Questionnaire (CSHQ)
- Pittsburgh Sleep Quality Index (PSQI)
- Vineland Adaptive Behavior Scales (VABS) -- Parent/Caregiver Interview Form
- Perceived Stress Scale (PSS)
- Caregiver Strain Questionnaire (CGSQ)
- General Functioning Scale (GFS)
- Contact Form & Demographics
- Compensation Form

Attach any unpublished instruments in the 'Other Study Documents' section of the Initial Review Submission Packet form after completing the study application. Published instruments should NOT be attached.

7.12 * BIOSPECIMEN COLLECTION: Are you drawing any blood or collecting other biosamples (e.g. tissue, buccal swabs, urine, saliva, hair, etc.) for analysis under this protocol and/or storage for future research: (REQUIRED)

○ Yes ◉ No

7.13 STATISTICAL METHODS: Briefly summarize the methods and types of analyses that will be performed:

Statistical Analyses will be conducted for Phase II. Descriptive analyses (e.g., mean, standard deviation, skewness) will be conducted for all variables of interest. For dependent variables of interest, distributions will be tested for normality and for homogeneity of variances across groups. If necessary, we will log transform the data to approximate a normal distribution. Provided that the data meet necessary requirements for employing parametric analyses, primary hypothesis testing for the proposed study will rely on repeated measures ANOVA (with time as the repeated factor with 2 levels; baseline and post-treatment) to investigate a time by treatment group interaction. We will use SPSS to conduct these analyses. We expect to be underpowered to detect effects but will use the mean differences to inform pilot data for larger grant.

7.14 REFERENCES: List only the 5-10 most relevant references (a separate bibliography can be attached for reference purposes if this study involves novel approaches, agents, or an emerging technology that the IRB may not be familiar with):

1. Malow BA, Marzec ML, McGrew SG, Wang L, Henderson LM, Stone WL. Characterizing sleep in children with autism spectrum disorders: a multidimensional approach. Sleep. 2006;29(12): 1563-1571.
2. Souders MC, Mason TB, Valladares O, et al. Sleep behaviors and sleep quality in children with autism spectrum disorders. Sleep. 2009;32(12):1566-1578.
3. Giannotti F, Cortesi F, Cerquiglini A, et al. An investigation of sleep characteristics, EEG abnormalities and epilepsy in developmentally regressed and non-regressed children with autism. Journal of autism and developmental disorders. 2008;38(10):1888-1897.
4. Wiggs L, Stores G. Sleep patterns and sleep disorders in children with autistic spectrum disorders: insights using parent report and actigraphy. Dev Med Child Neurol. 2004;46(6):372-380.
5. Mindell JA, Du Mond CE, Sadeh A, Telofski LS, Kulkarni N, Gunn E. Efficacy of an internet-based intervention for infant and toddler sleep disturbances. Sleep. 2011;34(4):451 458.
6. Wiggs L, France K. Behavioural treatments for sleep problems in children and adolescents with physical illness, psychological problems or intellectual disabilities. Sleep Medicine Reviews. 2000;4(3):299-314.
7. Giannotti F, Cortesi F, Cerquiglini A, Bernabei P. An open-label study of controlled-release melatonin in treatment of sleep disorders in children with autism. J Autism Dev Disord. 2006;36 (6):741-752.
8. Malow BA, Adkins KW, Reynolds A, et al. Parent-based sleep education for children with autism spectrum disorders. J Autism Dev Disord. 2014;44(1):216-228.
9. Reed HE, McGrew SG, Artibee K, et al. Parent-based sleep education workshops in autism. J Child Neurol. 2009;24(8):936-945.
10. Meltzer LJ. Brief report: sleep in parents of children with autism spectrum disorders. J Pediatr Psychol. 2008;33(4):380-386.

8.0 Drugs and Devices

8.1 * DRUGS AND/OR BIOLOGICS: Are you STUDYING any drugs and/or biologics that are either approved or unapproved: (REQUIRED)

○ Yes ◉ No

If you have questions about FDA requirements for drug or device research, you can send an email to request a consult.

8.3 * MEDICAL DEVICES: Are you STUDYING any medical devices, in vitro diagnostics, or assays that are either approved or unapproved:(REQUIRED)

◉ Yes ○ No

If you have questions about FDA requirements for drug or device research, you can send an email to request a consult.

8.4 * NSR: Are you requesting a Non-Significant Risk (NSR) determination for an investigational device: (REQUIRED) Note: an NSR determination is different from an Investigational Device Exemption (IDE). Check the Help link for more guidance on what types of devices can qualify for an NSR determination.

(•) Yes ( ) No

* Explain why the use of the device in this study poses a non-significant risk: **(REQUIRED)**

The devices do not meet the criteria for "significant" risk as listed above. The device is 1) not an implant, 2) will not supporting or sustaining human life, and 3) while it does help treat disease, it does NOT present a potential for serious risk to the health, safety, or welfare of a subject.

SweetDreams, an adaptation of existing evidence-based sleep interventions, is a user friendly and developmentally appropriate modularized 4-week web-based intervention; it is available on computer, tablet or mobile phones. It has three main components 1) didactic content via animated video learning modules, no longer than 7 minutes each, totaling 20 minutes per week (a link to the videos will be sent at the collaboratively predetermined time(s) via text message), 2) digital worksheets to personalize the recommendations that are discussed in the learning modules (requiring up to 10 minutes for completion), and 3) weekly telephone support (provided by Dr. Asarnow). Video learning modules will be hosted on password protected Vimeo™ platform using a unique password to enable usage monitoring.

Attach any documentation you have from the manufacturer and/or FDA to support this determination.

8.5 LIST THE DEVICES: List the medical devices or in vitro diagnostics to be studied or used. In the device details screen you will be asked questions such as:

- **Whether the device is FDA approved or investigational**
- **Medicare device category**
- **If the device will be provided at no cost**
- **If an IDE is necessary, the IDE number, and who holds the IDE**
- **Risk category of the device**
- **FDA status of the device**

Please see the UCSF IRB website for more details about the use of devices in research, including the Investigator Checklist for Significant Risk, Non-Significant Risk, and/or IDE Exempt Device Studies Verification of IDE numbers: If the sponsor's protocol does not list the IDE number, you must submit documentation from the sponsor or FDA identifying the IDE number for this study. Attach this documentation in the Other Study Documents section of the Initial Review Submission Packet. If you have any correspondence from the FDA or sponsor regarding this device, please attach it to the application.

View Details	Device Name	Is the Device FDA Approved	Is this a new device or a new use of an already approved device	IDE Number
⊟	SweetDreams	No	Yes	

Manufacturer/Supplier of Device	Principal Investigator
Medicare Category	☐ A ☐ B
Where will the Devices Be Stored	
Will Devices be supplied at no Cost	Yes
Is this a HUD (HDE)	No

HDE Number	
Is the Device FDA Approved	No
Is this a new device or a new use of an already approved device	Yes
Is an IDE necessary	No
IDE Number	
Who holds the IDE	N/A
IDE details	
In the opinion of the sponsor, select the level of risk associated with this device	No Significant Risk

8.6 * EXPANDED ACCESS: Is this an expanded access or compassionate use protocol, meaning the primary purpose is to diagnose, monitor or treat a patient's condition, rather than the collection of safety and efficacy data of the experimental agent: (REQUIRED)

○ Yes ◉ No

9.0 Sample Size and Eligibility Criteria

9.1 ENROLLMENT TARGET: How many people will you enroll:

30

If there are multiple participant groups, indicate how many people will be in each group:

For Phase I, we will recruit 10 children and their parents as part of the iterative intervention development process. For Phase II, we will conduct a small pilot randomized controlled trial with 20 children and their parents who will be randomized to one of two groups: (a) SweetDreams (n = 10) or (b) wait-list control (n = 10).

9.3 SAMPLE SIZE JUSTIFICATION: Explain how and why the number of people was chosen. For multi-site studies, this is referring to the number that will be enrolled across all sites:

All design decisions are guided by our overarching aim to promote future scalability to a population of children with ASD in clinics in community settings.

9.4 * PARTICIPANT AGE RANGE: Eligible age ranges: (REQUIRED)

- ☑ 0-6 years
- ☐ 7-12 years
- ☐ 13-17 years
- ☐ 18-64 years
- ☐ 65+

9.5 * STUDY POPULATIONS: Data will be collected from or about the following types of people (check all that apply): (REQUIRED)

- ☐ Inpatients
- ☑ Outpatients

- [x] Family members or caregivers
- [ ] Providers
- [x] People who have a condition but who are not being seen as patients
- [ ] Healthy volunteers
- [ ] Students
- [ ] Staff of UCSF or affiliated institutions
- [ ] None of the above

9.6 * SPECIAL SUBJECT GROUPS: Check the populations that may be enrolled: (REQUIRED)

- [x] Children / Minors
- [ ] Adult subjects unable to consent for themselves
- [ ] Adult subjects unable to consent for themselves (emergency setting)
- [x] Subjects with diminished capacity to consent
- [ ] Subjects unable to read, speak or understand English
- [ ] Pregnant women
- [ ] Fetuses
- [ ] Neonates
- [ ] Prisoners
- [ ] Economically or educationally disadvantaged persons
- [ ] None of the above

If not already addressed in the Background and Significance questions in the Research Plan section or elsewhere, explain why it is appropriate to include the types of subjects checked above in this particular study:

The study is designed to improve the care of a special vulnerable population -- minors diagnosed with Autism Spectrum Disorder. We believe that a non-pharmacological sleep intervention is safe and likely effective and may have benefits that extend beyond sleep, including improving the behavioral, cognitive and social functioning of children with ASD, as well as the mental health and wellbeing of their caregivers.

Describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects and minimize coercion or undue influence:

Here are some examples:

- evaluating capacity to consent for individuals who may be decisionally impaired (specify how)
- calibrating payment amounts to be non-coercive for the financially disadvantaged
- conducting more in-depth evaluations of subjects' understanding of the study and the voluntary nature of participation
- involving advocates in the consent process

More information and other safeguards are described here: **Vulnerable Subject Populations** and **Recruiting Staff and Students**.

The study intervention is delivered within the context of usual care services in the STAR clinic and the researchers will be able to refer to treatment providers as needed. Informed consent will clearly indicate the limits of confidentiality and that confidentiality may need to be broken if there is a safety concern.

9.7 INCLUSION CRITERIA: Briefly describe the population(s) that will be involved in this study. Include

anyone that data will be collected from or about (e.g. patients, healthy controls, caregivers, providers, administrators, students, parents, family members, etc.):

a) Age 12-72 months;

b) Poor sleep health defined by the Children's Sleep Habit Questionnaire (scoring 41 or higher);

c) A diagnosis of ASD;

d) Access to internet via computer, tablet, or smartphone

9.8 EXCLUSION CRITERIA: List any exclusion criteria (e.g. reasons why someone would not be included in the study):

a) Any regular sleep medication use (this does not include occasional over the counter sleep aid); and

b) Known sleep apnea, unstable major medical conditions (e.g. severe asthma, diabetes which is not managed)

9.9 * RESEARCH CONDUCTED ON PATIENT CARE WARDS: Do any study activities take place on any patient care units including inpatient wards, peri- or post-operative care units, operating rooms, or in the Emergency Department at UCSF Health medical facilities: (REQUIRED)

○ Yes ◉ No

9.11 * EMERGENCY DEPARTMENT: Does your protocol or study involve any of the following patient related activities in the emergency department (e.g. subject identification, recruitment, consent, blood draws, specimen retrieval, involvement of ED staff (nursing, tech, and/or physician), or any other ED based procedures): (REQUIRED)

○ Yes ◉ No

10.0 Inclusion of Minors in Research

10.1 REGULATORY CATEGORIES OF RESEARCH: Select all the regulatory categories that apply:

- [x] No greater than minimal risk (45 CFR 46.404, 21 CFR 50.51)
- [ ] Greater than minimal risk but presenting prospect of direct benefit (45 CFR 46.405, 21 CFR 50.52)
- [ ] Greater than minimal risk (though only a minor increase over minimal risk) and no prospect of direct benefit but likely to yield generalizable knowledge about the subjects disorder or condition (45 CFR 46.406, 21 CFR 50.53)
- [ ] Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407, 21 CFR 50.54)

Explain why the research in this study falls under the above category or categories:

We believe that the risks associated with this study are minimal compared to the knowledge that will be gained. Informed consent will clearly indicate the limits of confidentiality and that confidentiality may need to be broken if there is a safety concern.

10.2 **MINORS CONSENTING: Will this study enroll minors who can legally consent for themselves (as in the case of emancipated minors or minors being treated for pregnancy or drug use without their parents knowing). This is different from agreeing to be in the study even when their parents are the ones providing 'official' consent, which we refer to as 'providing assent':**

Note: This is very rare and the answer is usually 'No.'

○ Yes ◉ No

10.3 **PARENTAL PERMISSION VS. WAIVER: Please review the guidance to see under what circumstances the IRB can waive parental permission.**

- ☑ Parental permission will be obtained
- ☐ Waiver of parental permission is requested: The waiver meets the provisions for a waiver of consent (i.e., the research poses minimal risk, it could not practicably be carried out without the waiver of parental permission, AND the waiver will not adversely affect the rights and welfare of the minor participants (45 CFR 46.116(d))
- ☐ Waiver of parental permission is requested: Parental permission is not a reasonable requirement to protect the minor (e.g. neglected or abused children) or parental knowledge of the study may endanger the health or welfare of the minor (45 CRF 46.408(c))

Provide details on the other protections that will be in place:

i) Parental consent will be obtained by a TRAINED research assistant.

ii) Consent will be obtained in person at the study research space or at a private space in the clinic.

iii) There is no limit to the time allowed for discussion of consent. This process varies by subject. It is expected that most subjects will be able to reach a decision within 15 to 20 minutes.

vi) To minimize coercion, all subjects will be encouraged to ask questions and strongly discouraged from signing the consent without carefully reading it.

The person obtaining consent will go over the consent with the participant/parent, frequently pausing to inquire if the participant/parent understands or has questions. People who are not fluent in English enough to understand the consent or complete study interviews and questionnaires will not be enrolled. People with hearing impairment severe enough to prevent meaningful participation in therapy will be excluded. If level of impairment is minimal and participation is possible, the person obtaining consent will speak loud and slow and will ensure that the subject has not missed any information.

10.4 **ASSENT OF MINORS OR WAIVER: Please review the guidance to see under what circumstances the IRB can waive assent.**

- ☐ Assent of children developmentally and psychologically able to provide assent will be obtained
- ☑ Waiver of assent is requested: The capability of some or all of the children is so limited that they cannot reasonably be consulted
- ☐ Waiver of assent is requested: The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research
- ☐ Waiver of assent is requested: The activities involving the minor are limited to chart review or the something equally innocuous
- ☐ Waiver of assent is requested: It is not culturally appropriate to involve the minor in the decision to participate (e.g. some foreign research)

Provide a brief justification for the waiver:

Children will be between 12-72 months and diagnosed with Autism Spectrum Disorder.

10.5 DOCUMENTATION OF PERMISSION AND ASSENT: (select all that will be used):

- [x] Permission form addressed to the parents
- [ ] Simplified assent form addressed to the child, 7-12 years old (parents get separate form)
- [ ] Assent form addressed to the child, 13 years and older (for subjects and parents)
- [ ] Assent form addressed to the child, 13 years and older (parents get separate form)

Check one:

- (•) One parent's signature will be obtained
- ( ) Two parents' signatures will be obtained

If this study is approvable under regulatory category .405 and you plan to get permission from only one parent, explain why you think one parent's permission is sufficient:

10.6 WARDS OF THE STATE: Might this study enroll wards of the state:

( ) Yes (•) No

11.0 Recruitment and Consent

11.1 * COMPETITIVE ENROLLMENT: Is this a competitive enrollment clinical trial? By competitive enrollment, we mean that sites who do not enroll participants early may not get to participate at all: (REQUIRED)

( ) Yes (•) No

11.2 * SUBJECT IDENTIFICATION METHODS: What kinds of methods will be used to identify potential participants for recruitment (check all that apply): (REQUIRED)

- [ ] Review of patients' conditions, history, test results, etc. (includes patients seen in clinic, scheduled for surgery, a procedure, imaging, or tests, or seen in the Emergency Department as well as searching through medical record data for possible cohort identification)
- [ ] Already approved recruitment registry
- [ ] Re-contact of participants from the investigators' previous studies
- [ ] Referrals from colleagues (attach the 'Dear Colleague' letter or other recruitment materials you will provide to colleagues)
- [x] Referrals from the community / word of mouth
- [x] Advertisements (flyers, brochures, radio or t.v. ads, posting on clinical research sites or social media, presentation of the study at community events/media, etc.)
- [ ] Online recruiting tool (describe below)
- [ ] CTSI Recruitment Services unit
- [ ] Posting on UCSF Clinical Trials, ClinicalTrials.gov or other publicly available clinical trial website
- [x] Other method (describe below)

Attach your recruitment materials (e.g., flyers, ads, recruitment letter templates, email text, etc.) in the Other Study Documents section of the Initial Review Submission Packet Form.

* Provide details about the subject identification methods: **(REQUIRED)**

Children and their parent(s) will be recruited from the STAR Autism Clinic and the Division of Developmental Medicine. Eligible families will be given an information sheet describing the study when registering for their appointment. If families are interested in the study, they will be consented and asked to complete an initial screening measure. Families whose child screens

positive for sleep problems will be scheduled for a telephone screening to determine if all eligibility criteria are met. Eligible participants will then be scheduled for a baseline assessment and randomization.

Children and their parent(s) will also be recruited throughout the community, from recruitment ads posted on sources like online parents networks, county resource centers, etc. Recruitment ads will contain the study phone number, which interested parents can call to learn more about the study and determine eligibility.

Additionally, we will utilize SPARK's research match program for participant recruitment.

11.4 DETERMINATION OF ELIGIBILITY: How, when, and by whom will eligibility for recruitment be determined:

Children and their parent(s) visiting the STAR Autism Clinic will be given a contact sheet with information regarding the study when registering for their appointment. If interested, parents will complete the initial pre-screening questionnaire (Children's Sleep Habits Questionnaire (CSHQ), internet/mobile phone access, and English fluency) either via RedCap or a phone call. Eligible children and parents will be scheduled for consent and a screening interview to rule out exclusion criteria; we will use screening questions assessing current medication use, known sleep apnea, and unstable major medical conditions. Eligible children and parents will then participate in a baseline assessment and begin treatment. A research assistant (RA) will conduct all assessments (baseline, post-treatment and follow-up) using a combination of telephone interviews and online questionnaires. At the end of the baseline assessment, participants will be randomized to either the SweetDreams intervention condition or the waitlist control condition. If a family is randomized to receive the SweetDreams intervention, a research assistant (RA) will orient the parents to the treatment.

11.5 * INITIATION OF CONTACT: Who initiates contact (check all that apply): (REQUIRED)

- [x] Investigators/study team
- [ ] UCSF recruitment unit (e.g. CTSI Consultation Services)
- [x] Potential participant
- [ ] Other (explain below)

11.6 * HOW IS CONTACT INITIATED: (check all that apply): (REQUIRED)

- [ ] In person
- [x] Phone
- [ ] Letter / email
- [ ] Website or app
- [x] Other (explain below)

Attach the telephone recruitment script in the Other Study Documents section of the Initial Review Submission Packet Form. If potential participants will initiate contact, attach the telephone screening script that will be used to provide more information about the study and determine if callers are eligible to participate.

11.7 RECRUITMENT PLAN: Based on the checkboxes you chose above, please provide a narrative describing your recruitment plan. We want to know:

- **Who is conducting the search for potential participants, and how?**
- **How are potential subjects being approached for recruitment? By whom, and when?**

If there will be more than one participant group (e.g. patients, healthy controls, caregivers, family members, providers, etc.), provide details about the recruitment plans for each group. (Recommended length - 100-250 words)

Participants will be recruited from the STAR Autism Clinic and the Division of Developmental Medicine,. When parents register for their visits, they will be sent a contact sheet with information about the project. The contact sheet will explain that UCSF researchers are conducting a study on sleep for children with ASD. If interested and willing to speak with the research assistant (RA), the parent will complete a contact form. The RA will contact the parent to discuss the study within 2 business days. The RA will explain the study and conduct a phone screen to determine basic eligibility. Once a family is pre-screened and deemed eligible to continue, the RA will schedule a consent and screening interview visit. There, the RA will obtain consent from parents and the RA will cover the informed consent information thoroughly and answer any questions about the study. The signature of these forms will be gathered via docusign.

Children and their parent(s) will also be recruited throughout the community, from recruitment ads posted on sources like online parents networks, county resource centers, etc. Recruitment ads will contain the study phone number, which interested parents can call to learn more about the study and determine eligibility.

Additionally, we will utilize SPARK's research match program for participant recruitment.

11.8 * CONSENT METHODS: How will permission to participate (i.e., informed consent) be obtained from each potential participant. If there will be multiple groups and different plans for consenting each, check all that apply. See the orange Help bubble to the right for more detailed guidance. Participants will (check all that apply): (REQUIRED)

- [ ] Sign a paper consent form at the end of the consent discussion (signed consent)
- [x] Sign an electronic consent form using DocuSign (signed consent)
- [ ] Provide online consent through an app, a website, or a survey tool such as Qualtrics or REDCap (waiver of signed consent)
- [ ] Be told about the study and be given a handout/information sheet and be asked if they agree to participate (verbal consent - waiver of signed consent)
- [ ] Complete the study activities and turn in materials, as in the case of a completed survey that is placed in a drop box or mailed to the study team (implied consent - waiver of signed consent)
- [ ] Not be able to provide consent and will have a family member consent for them, as in the case of a critically ill or unconscious patient (surrogate consent)
- [ ] Not be able to provide consent (emergency waiver of consent - allowed for minimal risk research or greater than minimal risk research with an approved community consultation plan)
- [ ] Not know about the study, as in the case of chart reviews or observations of public behavior (waiver of consent)
- [ ] Other method (describe below)

As of Winter 2020, the UCSF Version of DocuSign is not Part 11 compliant. Part 11 compliance is required for FDA-regulated studies (studies using of investigational drugs or devices or studies of approved drugs or devices for investigational use). UCSF is currently pursuing a Part 11-compliant version of DocuSign. Please check the UCSF 21 CFR Part 11 Compliance webpage for updated information about the availability of Part 11-compliant DocuSign at UCSF.

11.9 * CONSENT PROCESS: Describe the process for obtaining informed consent, including details such as who will have the consent discussion and when participants will be asked to sign the consent form in relation to finding out about the study: (REQUIRED) We encourage researchers to review our guidance on obtaining and documenting informed consent.

- **If there are multiple groups being consented differently, provide details about the consent process for each group.**
- **If you are relying on verbal or implied consent, provide details about how that will happen.**
- **For studies using online recruitment and consent or consent via mail, provide details here.**

Consent will be obtained by a TRAINED research assistant who will go over the consent form with the participant via telephone/Zoom. Consent will be obtained via docusign. There is no limit to the time allowed for discussion of the consent. This process varies by subject. It is expected that most subjects will be able to reach a decision within 15 to 20 minutes. To minimize coercion, all subjects will be encouraged to ask questions and strongly discouraged from signing the consent without carefully reading it.

* It is important that the people obtaining consent are qualified to do so. Briefly describe the training and experience these individuals have in obtaining informed consent: **(REQUIRED)**

The Research Assistant will complete CITI training and will be trained personally by the Principal Investigator to ensure that all study protocols are understood and followed. In the first few months of the study the research assistant will shadow the PI while we develop a manual of operations, and recruitment protocol procedures. Following the first few months the research assistant will take primary responsibility for the study and will continue to meet with the PI once a week (at minimum) to ensure that the study protocol is being followed.

11.10 * CONSENT COMPREHENSION: Indicate how the study team will assess and enhance the subjects' understanding of study procedures, risks, and benefits prior to signing the consent form (check all that apply): (REQUIRED) Tip: Review the Consent Comprehension - Learning Notes in the Help bubble at the right for specific questions that can be asked to assess comprehension, consider using the UCSF Decision-Making Capacity Assesment Tool, and review our guidance on obtaining written or verbal informed consent for more detail on how to conduct the assessment.

- [x] The study team will engage the potential participant in a dialogue, using open-ended questions about the nature of the study or the experimental treatment, the risks and benefits of participating, and the voluntary nature of participation
- [ ] Potential participants will be asked or shown a series of questions to assess their understanding of the study purpose, procedures, risks and benefits, as well as the voluntary nature of participation (especially appropriate when the consent process happens online or through a mobile health app)
- [ ] Other method (describe below):

Provide details of the other approaches that will be used, if using another method to assess comprehension:

11.11 * DECEPTION: Does this study rely on some deception or misinformation about what the researchers are observing to get valid data? (REQUIRED)

○ Yes ◉ No

11.14 TIME: What is the estimated time commitment for participants (per visit and in total):

(i) Screening time: Pre-Screen 15 minutes AND Screening Interview 15 minutes
(ii) Active participation in the study:

- 60 minutes for post-treatment follow-up (Phase I) OR 30 minutes each for baseline and post-treatment follow-up assessment (Phase II),
- 120 minutes of active treatment time

(total of 210 minutes, or 3.5 hours)

It is anticipated that participants in both phases of the study will have similar time commitments.

IMPORTANT TIP: Ensure this information is consistent with the information provided in the consent form.

11.15 ALTERNATIVES: Is there a standard of care (SOC) or usual care that would be offered to prospective participants at UCSF (or the study site) if they did not participate in this research study:

- ○ Yes
- ◉ No

11.16 OFF-STUDY TREATMENT: Is the study drug or treatment available off-study:

- ○ Yes
- ◉ No
- ○ Not applicable

11.17 OTHER ALTERNATIVES: Describe other alternatives to study participation, if any, that are available to prospective subjects:

Alternative to online and in-person sleep treatment such as the SweetDreams Intervention is the use of hypnotic medications. However, to the best of our knowledge there are no data indicating that this alternative is superior to study interventions among children with Autism Spectrum Disorder.

12.0 Risks and Benefits

12.1 RESEARCH-RELATED RISKS: Check if your study involves any of these specific research-related risks to participants that may need to be disclosed in the consent form:

- ☐ Physical discomforts or pain
- ☐ Risks to employment, or social or legal standing
- ☐ Risk that the study team may observe possible evidence of child abuse, elder abuse, or a threat to self or others that they are required to report

12.2 * RISKS: Describe any anticipated risks and discomforts not listed above: (REQUIRED)

Risks associated with other procedures involved in the study as part of the data collection and measurement involve minimal risk. These include (a) the potential for loss of privacy and confidentiality; (b) legal limits to the confidentiality of information obtained if risk of harm to self or others, including children, is disclosed (in our experience, this has been very rare); and (c) some participants may consider the study measures timeconsuming, inconvenient, or otherwise disruptive of their usual routines. Time taken to attend study visits could also pose economic hardship. Subject payment are designed to offset this burden.

Another risk is associated with randomization. Subjects will be assigned to the treatment group or waitlist control group by chance, and it is possible that, if the treatment is effective, participants in the waitlist control group may experience a delay in improvement.

12.3 MINIMIZING RISKS: Describe the steps you have taken to minimize the risks/discomforts to subjects. Examples include:

- **designing the study to make use of procedures involving less risk when appropriate**
- **minimizing study procedures by taking advantage of clinical procedures conducted on the study participants**
- **mitigating risks by planning special monitoring or conducting supportive interventions for the study**
- **having a plan for evaluation and possible referral of subjects who report suicidal ideation**

Minimizing inconvenience: We try to minimize participant burden by offering participants the option to complete study measures online at their convenience, whenever feasible and assessments over the phone or zoom. In addition, efforts will be made to reduce inconvenience to participants by scheduling assessment and treatment sessions at times that are most convenient to them.

Minimizing risks of confidentiality: Protection of confidentiality will be accomplished by 1) assigning each participant a unique research ID that is not related to their PHI; 2) using HIPAA compliant school of medicine secure servers and encrypted and password protected computers for data collected and storage; 3) allowing access to any participant data only to authorized project staff that need to have access. No data will be extracted from the video platform. Participant data (questionnaires, worksheet responses, etc.) will be collected through REDCap.

For those individuals who are recruited via SFARI research match, participants will be asked to consent for the SPARK study, hosted by the Simons Foundation, to share with the University of California, San Francisco the clinical, demographic and genetic data collected during their participation in SPARK. Likewise, participants will be asked for consent to share the data collected during the study here at the University of California, San Francisco with SPARK in order to add to the information that was collected during your participation in SPARK. To safeguard confidentiality, all data-sharing will occur via a secure transfer system, and access to identifiable data will be limited to trained, authorized staff from SPARK and the study team. All shared data will be stored in encrypted folders that will be password-protected and/or require gated access.

12.5 * BENEFITS: (REQUIRED) Note: These are the benefits that the IRB will consider during their review. They are not necessarily appropriate to include in the consent form.

Possible immediate and/or direct benefits to participants and society at large (check all that apply):

- [x] Positive health outcome (e.g. improvement of condition, relief of pain, increased mobility, etc.)
- [x] Closer follow-up than standard care may lead to improved outcomes or patient engagement
- [x] Health and lifestyle changes may occur as a result of participation
- [x] Knowledge may be gained about their health and health conditions
- [x] Feeling of contribution to knowledge in the health or social sciences field
- [x] The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
- [ ] Other benefit (describe below)
- [ ] None

12.6 RISK TO BENEFIT RATIO: Explain why the risks to subjects are reasonable in relation to anticipated benefits, if any, to the participant or society:

We believe that the risks associated with this study are minimal compared to the knowledge that will be gained. Informed assent/consent will clearly indicate the limits of confidentiality and that confidentiality may need to be broken if there is a safety concern.

We expect that many patients will experience improved sleep and will gain knowledge about their sleep. The proposed study also offers clinical assessment for sleep disorders at no cost.
We believe that the risks associated with this study are minimal compared to the therapeutic benefits subjects receive from participating. We believe that by improving sleep of the child with ASD we will also positively impact his/her wellbeing and improve behavioral, cognitive, and social functioning, as well as reduce caregiver stress. Knowledge gained in this study will have the potential to eventually improve the treatment of sleep health deficits during childhood with broad potential public health benefits. We believe that the risks associated with this study are minimal compared to the knowledge that will be gained.

12.7 * DATA AND SAFETY MONITORING: Do you have a Data and Safety Monitoring Plan (DSMP) for this study (A DSMP is required for Greater than Minimal Risk research): (Click the Help link for guidance on risk determination) (REQUIRED)

○ Yes ◉ No

This is not required for minimal risk research but the UCSF IRB strongly recommends one to ensure the data collected are adequate to meet the research aims:

13.0 Confidentiality, Privacy, and Data Security

13.1 PROTECTING PRIVACY: Indicate how subject privacy will be protected:

- ☑ Conduct conversations about the research in a private room
- ☑ Ask the subject how they wish to be communicated with – what phone numbers can be called, can messages be left, can they receive mail about the study at home, etc.
- ☐ Take special measures to ensure that data collected about sensitive issues do not get added to their medical records or shared with others without the subject's permission
- ☐ Other methods (describe below)

13.2 SENSITIVE DATA: Do any of the instruments ask about illegal or stigmatized behavior:

○ Yes ◉ No

13.3 SIGNIFICANT CONSEQUENCES OF A LOSS OF PRIVACY OR CONFIDENTIALITY: Could a breach of privacy or confidentiality result in any significant consequences to participants, such as criminal or civil liability, loss of state or federal benefits, or be damaging to the participant's financial standing, employability, or reputation:

○ Yes ◉ No

13.4 EXTRA CONFIDENTIALITY MEASURES: Explain any extra steps that will be taken to assure confidentiality and protect identifiable information from improper use and disclosure, if any:

To protect participants' confidentiality, numerical data will be used as unique identifiers and identifying information will not be stored with the data. Hard copy data will be maintained in locked storage, and electronic data stored on shared computer drives maintained by the university under rigorous firewall and password protection. Secured information linking participant's ID with protected heath information will be separated from the unidentified data. Consents will be kept in docusign. Only the PI and authorized study personnel will have access to the protected files. All study records will be stored in REDCAP and be accessible only to the PI and authorized members of the research team. No identifying information of any individual subject will ever be revealed in any public presentations or publications from the study. Text messages (used to deliver the modules to participants) for SweetDreams will use REDCAP, a HIPAA compliant server. Audio files of the qualitative exit interviews will be stored in REDCAP. Audio recordings will be destroyed upon completion of all data analyses.

13.5 * REPORTABILITY: Do you anticipate that this study may collect information that State or Federal law requires to be reported to other officials, such as elder abuse, child abuse, or threat to self or others: (REQUIRED)

◉ Yes ○ No

The confidentiality and privacy section of the consent form should include this as a possible risk of participation.

* Describe the types of reportable information the research team may encounter and provide the details of the reporting plan: **(REQUIRED)**

Types of reportable information: threat or danger to self/others, child abuse, elder abuse.

Any reports of child or elder abuse, or threat to others will be reported as mandated by the law.

13.6 CERTIFICATE OF CONFIDENTIALITY: Will this study obtain a Certificate of Confidentiality:

- ○ Yes
- ◉ No

13.7 SHARING OF RESEARCH RESULTS: Will there be any sharing of EXPERIMENTAL research test results with subjects or their care providers:

- ○ Yes
- ◉ No

13.9 * HIPAA APPLICABILITY: Study data will be: (REQUIRED)

- ☐ Derived from a medical record (e.g. APeX, OnCore, etc. Identify source below)
- ☐ Added to the hospital or clinical medical record
- ☐ Created or collected as part of health care
- ☐ Used to make health care decisions
- ☑ Obtained from the subject, including interviews, questionnaires
- ☐ Obtained ONLY from a foreign country or countries
- ☐ Obtained ONLY from records open to the public
- ☐ Obtained from existing research records
- ☐ None of the above
- ☐ Derived from the Integrated Data Repository (IDR) or The Health Record Data Service (THREDS) at SFGH

13.10 * IDENTIFIERS: Check all identifiers that will be collected and included in the research records, even temporarily: (REQUIRED)

- ☑ Names
- ☑ Dates
- ☑ Postal addresses (if only requesting/receiving zip codes check Yes to the Zip Code question below instead of checking this box)
- ☑ Phone numbers
- ☐ Fax numbers
- ☑ Email addresses
- ☐ Social Security Numbers*
- ☐ Medical record numbers
- ☐ Health plan numbers
- ☐ Account numbers
- ☐ License or certificate numbers
- ☐ Vehicle ID numbers
- ☐ Device identifiers or serial numbers
- ☐ Web URLs
- ☑ IP address numbers
- ☐ Biometric identifiers
- ☐ Facial photos or other identifiable images
- ☐ Any other unique identifier
- ☐ None

* Could study records include *ANY* photos or images (even 'unidentifiable' ones): **(REQUIRED)**

○ Yes ◉ No

13.12 * PATIENT RECORDS: Will health information or other clinical data be accessed from UCSF Health, Benioff Children's Hospital Oakland, or Zuckerberg San Francisco General (ZSFG): (REQUIRED)

○ Yes ◉ No

13.19 * DATA COLLECTION AND STORAGE: (check all that apply): (REQUIRED)

Collection methods:

- ☐ Electronic case report form systems (eCRFs), such as OnCore or sponsor-provided clinical trial management portal
- ☑ UCSF ITS approved Web-based online survey tools: Qualtrics or RedCap
- ☐ Other web-based online surveys or computer-assisted interview tool
- ☐ Mobile applications (mobile or tablet-based)
- ☑ Text Messaging
- ☐ Wearable devices
- ☑ Audio/video recordings
- ☐ Photographs
- ☐ Paper-based (surveys, logs, diaries, etc.)
- ☐ Other:

* What online survey or computer assisted interview tool will you use: **(REQUIRED)**

- ☐ Qualtrics (Recommended)
- ☑ RedCAP (Recommended)
- ☐ Survey Monkey (NOT recommended and may require UCSF ITS Security review)
- ☐ Other

* Data will be collected/stored in systems owned by (check all that apply): **(REQUIRED)**

- ☐ Study sponsor
- ☑ UCSF data center (including OnCore, RedCap, Qualtrics, and MyResearch)
- ☑ UCSF encrypted server, workstation, or laptop residing outside of UCSF data center
- ☐ Personal devices, such as laptops or tablets that are not owned or managed by UCSF
- ☐ SF VAMC
- ☐ Zuckerberg San Francisco General Hospital
- ☐ Benioff Children's Hospital Oakland
- ☐ Langley Porter Psychiatric Institution
- ☐ Other UCSF affiliate clinic or location (specify below)
- ☐ Cloud vendor such as Amazon Web Services (AWS), Salesforce, etc. (specify below)
- ☐ Other academic institution
- ☐ 3rd party vendor (business entity)
- ☐ Other (explain below)

13.21 * DATA SHARING: During the lifecycle of data collection, transmission, and storage, will identifiable information be shared with or be accessible to anyone outside of UCSF: (REQUIRED)

○ Yes ◉ No

14.0 Financial Considerations

14.1 * PAYMENT: Will subjects be paid for participation, reimbursed for time or expenses, or receive any other kind of compensation: (REQUIRED)

(•) Yes ( ) No

14.2 PAYMENT METHODS: Subjects payment or compensation method (check all that apply):

Payments will be (check all that apply):

- [ ] Cash
- [ ] Check
- [x] Gift card
- [ ] Debit card
- [ ] UCSF Research Subject Payment Card
- [ ] Reimbursement for parking and other expenses
- [ ] Other:

14.3 PAYMENT SCHEDULE: Describe the schedule and amounts of payments, including the total subjects can receive for completing the study:

- **If there are multiple visits over time, explain how payments will be prorated for partial completion**
- **If deviating from recommendations in Subject Payment Guidelines, include specific justification below**

We have found payment to our subjects to be strong incentive for participating in assessments. Thus, we are requesting funds to cover payments to each subject for interviews and assessment tasks. ($30 total (for all assessments) x 30 participants per year = $900 per year)

14.4 COSTS TO SUBJECTS: Will subjects or their insurance be charged for any study activities:

( ) Yes (•) No

15.0 Other Approvals and Registrations

15.4 OTHER APPROVALS: Indicate if this study involves other regulated materials and requires approval and/or authorization from the following regulatory committees:

- [ ] Institutional Biological Safety Committee (IBC)

Specify BUA #:

- [ ] Institutional Animal Care and Use Committee (IACUC)

Specify IACUC #:

- [ ] Controlled Substances

16.0 Qualifications of Key Study Personnel and Affiliated Personnel

NEW: January 2019 - Affiliated personnel who do not need access to iRIS no longer need to get a UCSF ID. Instead, add them below in the Affiliated Personnel table below.

16.1 Qualifications of Key Study Personnel:

Instructions:

For UCSF Key Study Personnel (KSP)* listed in **Section 3.0,** select the KSP from the drop down list and add a description of their study responsibilities, qualifications and training. In study responsibilities, identify every individual who will be involved in the consent process. Under qualifications, please include:

- Academic Title
- Institutional Affiliation (UCSF, SFGH, VAMC, etc.)
- Department
- Certifications

NOTE: This information is required and your application will be considered incomplete without it. If this study involves invasive or risky procedures, or procedures requiring special training or certification, please identify who will be conducting these procedures and provide details about their qualifications and training. Click the orange question mark for more information and examples.

Training Requirements:
The IRB requires that all Key Study Personnel complete Human Subjects Protection Training through **CITI** prior to approval of a new study, or a modification in which KSP are being added. More information on the CITI training requirement can be found on our **website.**

* **Definition of Key Study Personnel and CITI Training Requirements (Nov, 2015):** UCSF Key Study Personnel include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of the research. Key Personnel also include faculty mentors /advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application.

KSP Name	Description of Study Responsibilities - Briefly describe what will each person be doing on the study. If there are procedures requiring special expertise or certification, identify who will be carrying these out. Also identify who will be obtaining informed consent.	Qualifications, Licensure, and Training
	The PI will oversee overall management of the study. More specifically the PI	

Dr. Asarnow, Lauren D PhD	will: -Meet with the CRC weekly to ensure that recruitment, assessments and data collection targets are all being met. -Ensure that all study procedures are on target. -Be available for clinical consultation as well as clinical emergencies. -Consult with the DSMB as needed to ensure that all study procedures are on target.	Dr. Asarnow (PhD) is an Assistant Professor, Department of Psychiatry and UCSF Weill Institute for Neurosciences. She is also a licensed Clinical Psychologist.
Dr. Leventhal, Bennett MD	The Primary Mentor will: -Work on developing and managing the overall research plan as well as all elements of the protocols -Assist with recruiting, enrollment, phenotyping, developing research strategies, tools and operations -Have a particular role in developing and monitoring the clinical intervention.	Dr. Leventhal (MD) is a Professor of Child and Adolescent Psychiatry at UCSF. He has extensive clinical and research experience in the area of neurodevelopmental disorders.
Dr. Bush, Nicole PhD	The Co-Mentor will: -Support Dr. Asarnow in her proposed research, both through scientific and intervention mentorship, as well as through providing support in recruitment of her target population through our clinical programs.	Dr. Bush (PhD) is an Associate Professor of Psychiatry and Pediatrics and the Division Chief (Director) of the Division of Developmental Medicine in the Department of Pediatrics at UCSF.
Mirchandaney, Riya	The CRC will will assist Dr. Asarnow in executing the study. More specifically the CRC will: -recruit and screen participants, manage assessments, scheduling, data collection, and other administrative aspects of study operations. - meet weekly with Dr. Asarnow	Riya Mirchandaney has a B.A. in Psychology and experience as an undergraduate RA at Columbia University working on sleep and mental health interventions.

16.2 Affiliated Personnel:

Instructions:

This section is for personnel who are not listed in **Section 3.0: Grant Key Personnel Access to the Study** because their names were not found in the User Directory when both the iRIS Database and MyAccess directories were searched. Add any study personnel who fit ALL of the following criteria in the table below:

- They meet the definition of Key Study Personnel (see above), **and**
- They are associated with a UCSF-affiliated institution (e.g., VAMC, Gladstone, Institute on Aging, Vitalant, NCIRE, SFDPH, or ZSFG), **and**
- They do not have a UCSF ID, **and**
- They do not need access to the study application and other study materials in iRIS.

Note: Attach a **CITI Certificate** for all persons listed below in the **Other Study Documents** section of the **Initial Review Submission Packet Form** after completing the **Study Application**.

Click the orange question mark icon to the right for more information on who to include and who not to include in this section.

Do not list personnel from outside sites/non-UCSF-affiliated institutions. Contacts for those sites (i.e. other institution, community-based site, foreign country, or Sovereign Native American nation) should be listed in the **Outside Sites** section of the application.

If there are no personnel on your study that meet the above criteria, leave this section blank.

Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this IRB Study				

Please describe the study responsibilities and qualifications of each affiliated person listed above:

17.0 End of Study Application

End of Study Application Form

To continue working on the Study Application:
Click on the section you need to edit in the left-hand menu. Remember to save through the entire Study Application after making changes.

If you are done working on the Study Application:
Important: Before proceeding, please go back to Section 4.0 Initial Screening Questions and **Save and Continue** through the form to make sure all the relevant sections and questions have been included. If you've changed any answers since you started, the branching may have changed. Your application will be incomplete and it will have to be returned for corrections.

Once you are sure the form is complete, click **Save and Continue**. If this is a new study, you will automatically enter the **Initial Review Submission Packet Form**, where you can attach **consent forms** or other **study documents**. Review the **Initial Review Submission Checklist** for a list of required attachments.

Answer all questions and attach all required documents to speed up your approval.

The UCSF IRB welcomes feedback about the IRB Study Application Form. Please click the link to answer a **survey** about the application form.

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Feasibility of a Sleep Intervention for Children with Autism Spectrum Disorder (SweetDreams) Study

Research Project Director:	Lauren Asarnow, PhD, Assistant Professor, Department of Psychiatry and UCSF Weill Institute for Neurosciences. 401 Parnassus Avenue, RM LP-A307, San Francisco, CA 94143 Phone: (415) 502-4561; e-mail: Lauren.Asarnow@ucsf.edu

Study Coordinator:	Riya Mirchandaney, Phone: (415) 502-4561; email: Riya.Mirchandaney@ucsf.edu

Dr. Asarnow, PhD from the UCSF Department of Psychiatry and UCSF Weill Institute for Neurosciences, is conducting a research study to learn more about a web-based health intervention and its effectiveness in improving sleep and behavior in children with Autism Spectrum Disorder.

STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You were selected as a possible participant in this study because your child is between 12 and 72 months old, has a diagnosis of Autism Spectrum Disorder and has reported sleep problems.

Why is this study being done?

The purpose of the Feasibility of a Sleep Intervention for Children with Autism Spectrum Disorder (SweetDreams) Study is to learn more about ways to provide effective behavioral sleep interventions among children with ASD. Behavioral sleep interventions are a type of counseling to help people improve their sleep habits and think in a healthy way about their sleep.

This study is funded by the Clinical & Translational Science Institute (CTSI). The study investigators have no conflict of interest regarding financial or proprietary interests. The study device is a web-based health program and is not FDA approved.

How many people will take part in this study?

This research study is looking for about 20 individuals to participate in the study.

What will happen if my child and I take part in this research study?

If you decide to enroll in this study, you and your child's participation will take place over a 4-week period.

If you agree, the following procedures will occur:

1. You will be asked to answer questions during a screening visit to determine if you and your child meet the study criteria. You will be asked general questions about your child such as age and ethnicity and about your child's sleep, as well as other questions that will allow us to determine if your child meets all study entry criteria. This screening visit will take between 40 ~ 60 minutes and will happen over the phone.

2. If your child is determined to be eligible for the study, you and your child will enter the baseline part of the study, during which you will be asked more questions about your child and about yourself.

3. At the end of the baseline part of the study, you and your child will be randomized to either the SweetDreams intervention condition or the waitlist control condition, which will be determined by chance. Like the flip of a coin, you will have an equal chance of being assigned to either group. Neither the investigators nor you can request or pre-specify which condition you will be assigned to.

4. If you and your child are randomized to the SweetDreams intervention, you will then receive a behavioral sleep intervention using a program called SweetDreams. We will provide you a code that will give you access to the program.

5. If you and your child are randomized to the waitlist control condition, you will be given access to the SweetDreams intervention after a 4-week waitlist period.

During the study, you and your child will be asked to:

1. Complete Study Assessments that will occur at baseline and at 4 weeks thereafter. If you are in the waitlist condition you will be asked to complete an additional assessment at 8 weeks. At each assessment you will complete questionnaires.

2. When you and your child are assigned to the SweetDreams intervention group: Engage in the SweetDreams intervention. The SweetDreams Intervention is a user friendly 4-week web-based intervention, available on mobile phones or other devices. It has two components 1) 20-minutes of weekly animated video learning modules, and 2) 5-10 minutes of digital worksheets to personalize the recommendations from the learning modules one or two times per week. Video learning modules will be hosted on a password-protected Vimeo™ platform and delivered via REDCap. No data regarding usage will be collected, except for timestamps when you open the REDCap link and when you mark the form as complete.

How long will my child and I be in the study?

You and your child's participation in this study will last about 4 weeks. This period includes screening, baseline, 4 weeks of either the intervention or the waitlist control and a final study visit that will take place immediately after the 4 weeks. If you are in the waitlist condition you will be asked to complete an additional assessment at 8 weeks. The total amount of time dedicated to the study (including all study visits and engagement with the intervention) is estimated to be 210 minutes (3.5 hours).

Can my child and I stop being in the study?

Yes. You and your child can decide to stop at any time. Just tell the study researcher or staff person right away if you or your child wish to stop being in the study. Also, the study researcher may stop you and your child from taking part in this study at any time if they believe it is in your or your child's best interest, if you or your child do not follow the study rules, or if the study is stopped.

What side effects or risks can my child and I expect from being in the study?

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. If you have questions, please ask. You may contact the study team if you have any questions about the intervention. The risks associated with this study are minimal.

- Some of the questions in the interviews and questionnaires are of a personal nature and could possibly be emotionally upsetting (e.g. questions about caregiving stressors, family conflict, etc.).
- Some children experience increased daytime sleepiness in the early stages of one of the sleep therapies being provided in this study. Typically, if sleepiness emerges as a side effect of the intervention, it disappears as the intervention progresses. You should alert your study coordinator should your child experience an increase in sleepiness.
- Some individuals may find it stressful to try new behavioral strategies with their children. Relatedly, some children may find it stressful to develop new routines and may act out in response to new limits.
- Randomization risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments. If the intervention (SweetDreams) were to be effective and your child is placed in the non-treatment (wait-list control) group, this would mean that your child's treatment will be delayed by 4 weeks (one month).
- The study intervention or procedures may involve risks that are currently unforeseeable.
- It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.
- Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.
- For more information about potential risks, ask one of the researchers.

Are there benefits to taking part in the study?

You may benefit from participating in the study (i.e. there may be improvements in your child's sleep and associated daytime impairment), but this cannot be guaranteed. Your child's participation may provide the investigators valuable data, which may lead to advances in the intervention of individuals with sleep problems and increased access to this type of mental health care.

You and your child's participation and time, therefore, may ultimately lead to broader benefits for society and for people who experience problems sleeping. We cannot and do not guarantee or promise that your child will receive any benefits from this study. You and your child's decision whether or not to participate in this study will not affect you or your child's medical care.

What other choices do I have if I do not take part in this study?

The web-based intervention that you and your child will be receiving as part of their participation in the study is a standard intervention for sleep concerns. Another standard intervention for sleep problems that is not provided in this study is taking a sleep medication or in-person therapy. Your child's participation does not preclude their engagement in any intervention for sleep problems outside the study (but please tell us about it). In addition, you and your child may choose not to participate in this research study.

You and your child are free to choose not to participate in the study. If you and your child decide not to take part in this study, there will be no penalty to you or your child. You and your child will not lose any of your regular benefits, and you and your child can still get your care from our institution the way you usually do.

Will information about my child be kept private?

Participation in research involves some loss of privacy. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

If information is revealed about child abuse or neglect, elder or dependent abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Although participation in research may involve a loss of privacy, information about you and your child will be handled as confidentially as possible.

For those individuals who participated in the SPARK study, we are asking your consent for the SPARK study, hosted by the Simons Foundation, to share with the University of California, San Francisco the clinical, demographic and genetic data collected during your participation in SPARK. This information will be shared using your linked research ID number and using a secure transfer system.

We are also asking for your consent to share the data we collect during the study here at the University of California, San Francisco with SPARK in order to add to the information that was collected during your participation in SPARK. Please note that because you are a participant in both studies, SPARK and this study will be able to share and link your identifying information as well as any future data you may contribute to either project. To safeguard your confidentiality, all data-sharing will occur via a secure transfer system, and access to identifiable data will be limited to trained, authorized staff from SPARK and the study team. All shared data will be stored in encrypted folders that will be password-protected and/or require gated access.

The Simons Foundation funds innovative research and provides coded data access (data with your identifying information removed) to qualified researchers. Researchers can file an application with the Simons Foundation to obtain access to your study data for research purposes. Experts at the Simons Foundation who protect health and science information will look at every request carefully to minimize risks to your privacy.

Are there any costs to me for taking part in this study?

No, there is no cost for you or your child for taking part in the study.

Will I be paid for taking part in this study?

In return for your time, you and your child will be paid a gift card worth a total of $30, regardless of which group you are assigned to.

What happens if my child and/or I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Asarnow, if you feel that you or your child have been injured because of taking part in this study. You can tell the doctor in person or call them at 415-502-4561.

Treatment and Compensation for Injury: If you or your child are injured as a direct result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do. You and your child are also free to participate in other research studies.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact Dr. Asarnow at Lauren.Asarnow@ucsf.edu or 415-502-4561.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

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

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw your child from it at any point without penalty or loss of benefits to which you or your child are otherwise entitled.

The participant being considered for this study is unable to consent for themselves because they are a minor. By signing below, you are giving your permission for your child to be included in this study.

Date	Parent or Legal Guardian
Date	Person Obtaining Consent