Title:	**Beds for Kids Program: Impact on Child Sleep and Family Functioning in Young Children**
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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
BMI	Body Mass Index
IRB	Institutional Review Board
EMR	Electronic Medical Record
OHAAT	One House at a Time
PHI	Protected Health Information
RCT	Randomized Controlled Trial
REDCap	Research Electronic Data Capture
SES	Socioeconomic status
WCV	Well Child Visit

ABSTRACT

Context:

Many lower-socioeconomic status (SES) children live in crowded homes and lack their own bed, which can contribute to insufficient and poor quality sleep and related poor child and family functioning. The Beds for Kids program provides beds and bedding to disadvantaged children in Philadelphia, and has been found to positively impact parent-reported child sleep in a previous pilot study. However, there is a need to determine the impact of the Beds for Kids program on objectively assessed child sleep, as well as on daily child behavior and caregiver functioning (mood and sleep).

Objectives:
The primary study objective is to evaluate the impact of provision of a child bed through the Beds for Kids program on objectively measured child sleep, and on daily child behavioral functioning and caregiver functioning over a 14-day period for preschool-aged children.

Secondary objectives are:

- To determine the impact of poor child sleep (short sleep duration, later bedtimes, inconsistent bedtimes, night wakings, and poor caregiver-rated sleep quality) on daily child behavior and caregiver functioning (mood and sleep).
- To determine the impact of provision of a child bed through the Beds for Kids program on child sleep at one-month follow-up.
- To identify caregivers' perceptions of barriers to and facilitators of sleep health and behavioral sleep treatment.

Study Design:
This is a randomized controlled trial (RCT). Caregiver-child dyads will be assigned to the intervention group, in which they receive a bed through the Beds for Kids program after a 7-day period, or to the waitlist control group, in which they receive a bed after a 14-day period.

Setting/Participants:

This is a single site study to be performed at CHOP. A total of 50 caregiver-child dyads (child age 2 to 5 years) will be recruited from clinicians at CHOP primary care sites. Families must be eligible for the Beds for Kids program: (a) child is living without his/her own bed and (b) family is at or below 100 percent of the Federal Poverty Guideline.

Study Interventions and Measures:

Caregivers in the intervention and waitlist control conditions will complete measures of child sleep and behavior, as well as caregiver functioning (mood; resilience; sleep) and family functioning (i.e., chaos). Over a 14-day period, children in both study conditions will wear actigraphs to objectively measure sleep, and caregivers will complete daily ratings of child behavior, caregiver mood, and caregiver sleep. At one-month after bed delivery, caregivers will complete measures of child sleep and behavior. At one-month follow-up,

caregivers will also be given the option to participate in a brief, semi-structured qualitative interview related to barriers to and facilitators of sleep health and behavioral sleep treatment.

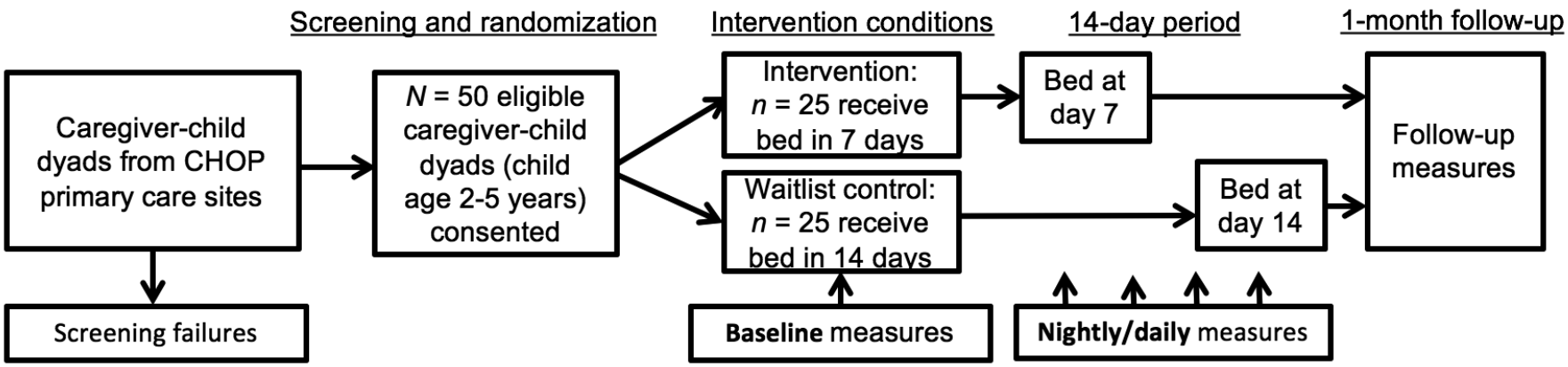
The primary study outcome is the difference between study conditions in actigraph-derived and caregiver-reported child sleep (bedtime, bedtime variability, sleep quality, night wakings, total sleep duration) for days 7 to 14 (bed vs control), as well as compared to baseline. Thus, this is a mixed between (bed vs waitlist) and within (days 1-7 vs days 8-14) group design.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**Screening**	**Baseline and Intervention**															**One month Follow-up**
Visit Number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
Approximate Study Days (May vary by 7 days)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**36-43 (dependent on bed delivery date)**
Chart review	X																
Verbal Informed Consent	X																
Review Inclusion/Exclusion Criteria	X																
Randomization	X																
Caregiver-reported caregiver and family demographic information		X															
Caregiver-reported child sleep and behavioral measures, caregiver resilience, mood, and family chaos measures		X															X
Medical record review and child demographic data abstraction		X															
Actigraphy (objective sleep measurement)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Caregiver-reported daily questionnaire (caregiver and child sleep and mood)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Bed provision (day 7 for intervention group; day 14 for waitlist control group)									X							X	
Caregiver semi-structured interview about barriers to and facilitators of sleep health and behavioral sleep treatment																	X
Adverse Event Assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

.

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Insufficient and/or poor quality sleep is associated with a number of adverse developmental outcomes, including diminished neurocognitive, behavioral, physical health, and family functioning.[1-7] While many young children experience insufficient sleep,[8-10] research indicates that socioeconomically disadvantaged youth tend to obtain less sleep overall and experience worse sleep quality, as well as increased sleep disturbances, compared to their higher-income peers.[11-15] Many children of lower socioeconomic status (SES) live in noisy or high-violence neighborhoods,[16] and in overcrowded homes that lack a child bed or other designated child sleep space, which may perpetuate health disparities in child sleep problems.[17,18] Our previous pilot study conducted in collaboration with the Philadelphia area Beds for Kids program,[23] which provides a bed and bedding to lower-SES children, found that simply providing a child with a bed can improve caregiver-reported child nighttime sleep duration and other sleep habits, such as the use of electronics in the bedroom. However, these findings were based on a brief, 6-question caregiver-reported survey conducted at baseline and at one-month follow-up. Thus, there is a need to determine the impact of the provision of beds on objectively assessed child sleep, as well as on daily child behavior, caregiver mood, and caregiver sleep. Few studies have examined *daily total* child sleep patterns and related developmental outcomes among children of lower SES, and even fewer studies have examined the *daily* impact of poor sleep on child behavior and family functioning. Thus, the purpose of this study is to better understand how the provision of beds, in programs such as Beds for Kids, may positively impact objectively measured child sleep, as well as daily levels of child and family functioning. As a number of developmental changes occur between the ages of 2 and 5 years, promoting healthy sleep during early childhood is critical, thus young children are the focus of this study.

1.2 Name and Description of Investigational Product or Intervention

The Beds for Kids program, which is part of the non-profit organization One House at a Time, gives every child in the program a new twin-size bed mattress, metal bedframe, and a "bedtime bag," which contains a sheet set, blanket, pillow, several books, stuffed animal, and toothbrush. Children also receive educational messages about healthy sleep habits via a magnet and "color-your-own" bookmark. All of the items are sorted, packaged, and delivered directly to program recipients in their homes.

1.3 Relevant Literature and Data

Sleep is a modifiable behavior that is germane to the prevention of broad pediatric psychosocial impairments and health concerns. Obtaining too little sleep is associated with a number of negative developmental consequences, including diminished behavioral and neurocognitive functioning,[1-3] and poor physical health[4-6] and family functioning.[7] Although insufficient sleep and bedtime problems impact up to 20-30% of toddlers, preschoolers, and kindergarteners,[8-10] children of lower SES, who are disproportionately of racial/ethnic minority background, are more likely to experience poor and insufficient sleep

relative to their higher-income peers.[11-16] Studies have shown that shorter sleep duration, later and less consistent bedtimes,[11-13] more frequent night awakenings, and poor sleep quality are more common among lower-SES children,[14-16] who are also less likely to have access to specialty care services to address sleep issues.[17, 18] However, few studies have examined the *daily total* sleep patterns of lower-SES children,[19] while even fewer studies have examined how these patterns may impact *daily* levels of child and family functioning.[20]

Given the number of physical, neurocognitive, and social-emotional changes that occur between the ages of 2 and 5 years, promoting healthy sleep during this developmental period is critical. A recent study of kindergarteners undergoing screening for entry into first grade found that children deemed unfit for first grade had a shorter sleep duration and more night awakenings relative to their peers.[2] Furthermore, experimental research has also shown that restricting sleep in 2- and 3-year-olds negatively impacts emotion regulation,[22] which is a developmental skill that is necessary for positive behavioral functioning and broad school readiness.

It is especially important to promote healthy sleep patterns among low-SES children, who are at-risk for developing sleep disorders,[11-15] and are often living in overcrowded conditions without a designated sleep space.[16] Sleeping in a noisy, crowded environment or shared living space can result in inconsistent child bedtime routines and schedules, frequent nighttime awakenings, and shorter sleep duration.[16, 23] Sleeping on a couch or bed-sharing may also increase child exposure to electronics,[23] such as television and mobile phones, at bedtime and during the night, which negatively impacts young children's sleep quality and duration.[24, 25] Insufficient and poor quality sleep among young children can additionally contribute to family stress. Child sleep problems are associated with worse maternal mood, parenting stress, and disrupted caregiver sleep.[7] Although caregiver resilience may buffer the negative effects of child sleep on caregiver mood, such associations may be intensified in lower-SES contexts, where families contend with multiple economic hardships and stressors.[16]

Research is needed to examine whether improving the sleep environment of lower-SES children can positively impact objectively measured child sleep, as well as daily child behavior, caregiver mood, and caregiver sleep. Beds for Kids, a Philadelphia-area program that is part of the larger volunteer organization, One House at a Time, aims to improve the sleep environment of lower-SES children by providing these youth with beds, bedding, and a sleep education brochure. To quality for program participation, youth must be: (1) between the ages of 2 and 20 years, (2) living without an individual bed (e.g., sleeping on the floor, on a sofa, or crowded into one bed with family members), and (3) living in a household whose income is at or below 100 percent of the US poverty threshold. The program accepts referrals from area social service agencies, as well as from Children's Hospital of Philadelphia (CHOP) primary care clinics in the greater Philadelphia area.

We recently collaborated with the Beds for Kids program to evaluate the effect of receiving a bed versus receiving a bed plus parent-based sleep education in children ages 2 to 12 years[23]. In addition to receiving a bed, 152 children (57% male; mean age 5.95 years) were randomly assigned to sleep education (3 messages: bedtime before 9:00 PM, no caffeine; no electronics in the bedroom) or control (dental hygiene education) conditions. Caregiver reported sleep data using a 6-item survey collected at baseline (bed delivery) and 4-week

follow-up showed that **simply receiving a bed was associated with reduced bedroom electronics and increased nighttime sleep duration for all children.**[23] Children whose parents received sleep education also showed greater reductions in electronics and improvements in sleep duration. However, this study was limited in that we did not objectively assess child sleep, and relied on retrospective caregiver reports.

Research is also needed on lower-SES caregivers' perceptions about barriers and facilitators to healthy sleep habits. There is a paucity of research on sleep health promotion and behavioral sleep intervention strategies among lower-SES families.[23] The stressors identified above that may contribute to poor sleep in lower-SES children, including crowded and noisy living conditions, lack of an individual bed, and other economic hardships,[16, 23] may similarly make it difficult for families to implement healthy sleep habits. More studies are needed to better understand families' perceptions about factors that may undermine or facilitate sleep health and evidence-based behavioral sleep promotion activities, such as the sleep education provided as part of the Beds for Kids program. This information will help to inform future efforts to effectively tailor sleep education and other strategies to promote sleep health in lower-SES families.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The **overall goal** of this pilot study is to obtain a better understanding of the sleep patterns of lower-SES preschoolers through the evaluation of the effects of providing socioeconomically disadvantaged children with a bed through the Beds for Kids program on child sleep, as well as on daily child behavior, caregiver mood, and caregiver sleep.

2.1 Primary Objective (or Aim)

The primary objective of this study is to evaluate the impact of provision of a child bed through the Beds for Kids program on objectively measured child sleep, and on daily child behavioral functioning, caregiver mood, and caregiver sleep over 14 days for preschool-aged children.

- Hypothesis 1a: Children who receive a bed will have improved sleep health (longer total sleep duration, earlier bedtimes, more consistent bedtimes, decreased night wakings, and better sleep quality) relative to children in the study waitlist condition (i.e., those who receive a bed after the full 14-day period).
- Hypothesis 1b: Children who receive a bed will show better behavioral functioning and

increased caregiver-reported mood and sleep relative to children in the study waitlist condition.

2.2 Secondary Objectives (or Aim)

There are three secondary objectives:

(1) To determine the impact of poor child sleep (short sleep duration, later bedtimes, inconsistent bedtimes, night wakings, and poor sleep quality) on daily child behavior, caregiver mood, and caregiver sleep.

- Hypothesis 2a: Worse child sleep on one night will be associated with worse child behavior and diminished caregiver nighttime sleep and caregiver mood the following day.
- Hypothesis 2b: The effects of poor sleep will be cumulative, such that children with poor sleep across multiple nights will exhibit the worst child behavior, with the lowest caregiver mood and worst caregiver sleep, over the two-week study period.

(2) To determine the impact of provision of a child bed through the Beds for Kids program on child sleep at one-month follow-up (one-month post-bed delivery).

- Hypothesis 3a: Receiving a bed will be associated with improved sleep health (longer total sleep, earlier bedtimes, more consistent bedtimes, decreased night wakings, and better sleep quality) from baseline to one-month follow-up across study conditions.

(3) To identify caregivers' perceptions of barriers and facilitators related to sleep health and potential behavioral sleep treatment (one-month post-bed delivery).

- This is an exploratory aim.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Screening and Randomization Phase

Clinicians at the Chestnut Hill, South Philadelphia, Karabots, and Cobbs Creek locations who are already referring families directly to the Beds for Kids program will identify potentially eligible families for this study. Families who are eligible for Beds for Kids will then be asked whether they would be interested in participating in a research study related to the program. The clinician will provide the name, MRN, and contact information of interested families to the study team. The study team will then conduct an initial medical record review to identify whether the referred family is potentially eligible. The study team will then contact the potentially family to initiate informed consent and eligibility screening procedures. Alternatively, families receiving care at any of the CHOP primary care recruitment sites (Chestnut Hill, South Philadelphia, Karabots, or Cobbs Creek) may self-refer to the study if they hear of the Beds for Kids program through word-of-mouth or social

media (e.g., Facebook). However, we will not advertise the study on social media of any kind for recruitment purposes.

The informed consent process will take place by phone, with a member of the study team obtaining verbal consent from the legal guardian for study participation. Child assent will not be obtained as all participating children are under age 5 years. Families will be informed that they are free to decline to participate or to withdraw from the study, and that this will not impact their participation in the Beds for Kids program or any future medical care. After obtaining verbal informed consent, families will be screened for study inclusion and exclusion criteria.

Eligible families will be randomly assigned to receive a bed from Beds for Kids 7 days after initiating the actigraph/daily diary study procedures (intervention condition), or to receive a bed 14 days after initiating these procedures (waitlist control condition). Thus, this is a mixed between (bed vs waitlist) and within (days 0-7 vs days 8-14) group design.

As bed delivery from the Beds for Kids program usually takes 1-2 weeks, this design does not interfere with the typical program practices and will not result in a bed delivery delay for participants in either condition. A member of the study team will call to schedule the family for their bed delivery, and to schedule a time to complete baseline measures.

3.1.2 Study Baseline and Treatment Phase (start of the study intervention)

During this phase, caregivers and the participating family meet with a member of the study team at Visit 1 to complete baseline caregiver-reported measures and to be fitted for an actigraph (for objective measurement of child sleep; see below). Visit duration for eligible participants at baseline is approximately 45 minutes.

As part of the baseline phase, a member of the study team will also abstract child electronic medical record (EMR) demographic and health information, which does not require the participants to be present.

Caregivers will be asked to complete daily caregiver-reported measures and to have the participating child begin wearing actigraph device for objective measurement of child sleep for Visits 2-14/days 1 through 14. Actigraph initiation will occur within 7 days of baseline survey completion. Details about these procedures are provided in sections 4 and 5, below.

3.1.3 Follow-up Phase

Caregivers in both study conditions will complete follow-up measures at one-month after bed delivery (visit 15; day 35 [+1-7 days] for intervention participants or day 42 [+1-7 days] for waitlist control participants). Study duration at follow-up for baseline surveys is approximately 30 minutes. At follow-up, families will also be given the option to verbally consent to participate in a brief (30-minute) semi-structured interview about sleep health and behavioral sleep treatment.

3.2 Allocation to Treatment Groups and Blinding

Participants will be randomly assigned by study statistician, Dr. Ji Young Kim, at a 1:1 ratio using code written into R statistical software. No stratification or blocking will be used. The Lead Investigator Dr. Williamson, PI Dr. Mindell, and Study Coordinator Mary Anne Cornaglia will not be blinded to condition assignment. However, all other members of the study team involved in data collection will be blinded to intervention group assignment. Blinding will be maintained by keeping a separate, password-protected list in REDCap that lists subject ID and group assignment. This database will be accessible only to the study statistician, PI (Dr. Mindell), Lead Investigator (Dr. Williamson), and study coordinator.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject will be approximately 42 days (+1-7 days) with 1 screening day (study day 0), 14 days for the baseline and intervention phase (days 1 through 14, +-7 days), and 1 follow-up day for the one-month follow-up assessment, which occurs on day 35 (+1-7 days; intervention participants) or day 42 (+1-7 days; waitlist control participants).

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

This study will be conducted only at the Chestnut Hill, South Philadelphia, Cobbs Creek and Karabots, all of which are CHOP-affiliated primary care sites in Philadelphia, PA.

Recruitment will stop when 50 caregiver-child dyads (100 subjects total) have completed the full study procedures, through the follow-up period.

3.4 Study Population

3.4.1 Inclusion Criteria

1) Males or females ages 2 to 5 years and their male or female caregiver reporter (legal guardian)

2) Eligible for the Beds for Kids program: (a) living without individual bedding (sleeping on the floor, on a sofa, or crowded into one bed with family members); (b) living in a household whose income is at or below 100 percent of the Federal Poverty Guideline.

3) Parent/guardian is English-speaking.

4) Caregiver is legal guardian and can complete informed consent.

3.4.2 Exclusion Criteria

1) Presence of a chronic medical (e.g., cancer, sickle cell disease) or neurodevelopmental (e.g., autism, Trisomy 21) condition that would impact sleep, including a pre-existing sleep disorder diagnosis (e.g., obstructive sleep apnea) in child.

2) Child or caregiver use of prescription (e.g., clonidine) or over-the-counter medication (e.g., Benadryl; melatonin) that could impact the child's sleep or caregiver report of child's sleep.

3) Caregivers/guardians or subjects who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures.

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening and Randomization: Visit 0 (study day 0)

- Review of medical record
- Verbal informed consent (by phone)
- Review of inclusion/exclusion criteria
- For eligible participants:
- Randomization to study condition: intervention or waitlist
- Scheduling of baseline visit (Visit 1)

4.2 Study Baseline and Treatment Phase: Visits 1 through 14

All participating caregivers will complete study baseline measures in person on Visit 1/study day 1. Families will be asked to complete daily measures and have their child wear an actigraph to objectively measure sleep for a 14-day period. If families do not complete a diary on the appropriate day, they will be given the opportunity to complete the diary on another day during the 14-day period. For the intervention group, the Beds for Kids program bed delivery will occur 7 days after initiating the acitgraph. For the waitlist control group, the bed delivery will occur 14 days after initiating the actigraph. The daily visits (by phone) reflect the same procedures for each visit day, with the exception of bed delivery.

4.2.1 Visits 1 through 14 (study days 1 through 15 +1-7 days)

Visit 1 (in person):

- Completion of electronic caregiver-reported demographic information
- Completion of electronic caregiver-reported child sleep, child behavior, caregiver resilience, caregiver mood, and family chaos questionnaires
- Provision of incentive for baseline measure completion
- EMR review and data abstraction of child demographic information by a member of the study team.

Visits 2 through 15 (by phone): Visit 2 will occur within 7 days of Visit 1.

- Actigraphy (objective measurement of child sleep)
- Completion of caregiver daily mood and sleep questionnaires by phone

- Completion of caregiver-reported child behavior and sleep questionnaires by phone
- Bed delivery (day 7 after actigraph initiation for intervention condition; day 14 after actigraph initiation for waitlist control condition)
- Provision of incentives for daily measure and actigraph completion
- Scheduling of return of actigraph to study team (during the week following Visit 15)

4.3 Follow-up Phase (only if applicable)

Caregivers will be contacted at one-month follow-up post-bed delivery (study day 36 [+1-7 days] for the intervention condition; day 43 [+1-7 days] for the waitlist control condition) to complete follow-up measures and a brief, semi-structured qualitative interview. The study will then end.

4.3.1 Visit 16: One month follow-up

- Completion of caregiver-reported child sleep and behavior follow-up questionnaires by phone or in-person.
- Option to consent for and complete in-person 30-minute semi-structured qualitative interview on sleep health and behavioral sleep treatments.

4.4 Unscheduled Visits

We do not anticipate any unscheduled visits as part of this study, although unscheduled phone contact may occur with some participants (e.g., clinically significant behavior/mood concern, issue with actigraph).

Clinically significant behavior/mood concern. Lead Investigator Dr. Ariel Williamson will contact the family within 3 business days of the study visit if the family reported clinically significant child behavior or caregiver mood concerns on validated questionnaires. Similarly, if a caregiver spontaneously reports concerns related to caregiver or child behavior or mood by phone with a member of the study team, that team member will notify Dr. Williamson, who will then contact the family within 3 business days. During an unscheduled phone call, Dr. Ariel Williamson will provide the family with appropriate community referrals for mental health services, as well as the information of the CHOP social workers employed at each of the primary care sites from which families were referred. In the case of clinically significant caregiver report of depressed mood, Dr. Ariel Williamson will also conduct a risk assessment over the phone. This risk assessment will contain questions about caregiver homicidal and suicidal ideation, and the presence of any homicide/suicide plan or intent, consistent with CHOP behavioral health risk assessment practices. Should there be an imminent safety risk, Dr. Williamson will contact emergency services (911 or Pennsylvania mobile crisis services) for further suicide/homicide/risk assessment. All information obtained during the risk assessment will be used only for the purposes of determining appropriate follow-up care. Information about child safety concern or mandated reporting will be documented in the child's medical record, and will not be stored with study data, or used for any study-related data analysis. It will not be stated in the medical record documentation that the child or caregiver are participating in a research study. For caregiver risk assessment procedures, risk assessment will be documented in a

Note to File coded by the participant ID and will be stored separately from the consent form and in a separate REDCap database used for tracking purposes only.

Actigraph issue. If there are any issues with the actigraph device, families will be encouraged to contact a member of the study team by phone. Any issues will be handled primarily via phone, although an in-person visit may occur if the family must be provided with a replacement actigraph.

Beds for Kids issue. If families encounter any difficulty with materials provided to them through Beds for Kids (e.g., mattress, bedframe), the family will be asked to contact Beds for Kids directly. We will inform families that in order to maintain their confidentiality and privacy in the study, we are unable to contact Beds for Kids on their behalf.

Other follow-up issue. If caregiver-child dyads that participated in the study contact the Dr. Jodi Mindell (PI) or Dr. Ariel Williamson (investigator) by phone to request follow-up, any issues will be handled via phone, without an in-person visit.

4.5 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, or AEs. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

4.5.1 Early Termination Study Visit

Subjects who withdraw from the study will have all procedures enumerated for Visit 16 at the early termination visit.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

Child demographic information

- Age
- Sex
- Race
- Ethnicity
- BMI
- Current medications
- Current diagnoses
- Zip code
- Contact information
- CHOP site where child receives primary care services

5.1.2 Other Evaluations, Measures

- Measures at baseline:
  - *Caregiver/family Demographic Questionnaire:* Caregivers will complete a caregiver and family demographic questionnaire. Caregiver/family data will include age, sex, race, ethnicity, highest educational level obtained, relationship to child, income, employment status, marital status, current public assistance, number of times the family has moved in the last year, and number of children and adults living in the home.
  - *Brief Child Sleep Questionnaire (BCSQ):* Caregivers will complete the 30-item BCSQ[28, 29] to report on child sleep habits (sleep time, day/night sleep duration, night wakings, aspects of the sleep environment, etc.) and the severity of any caregiver-perceived sleep problems. The BCSQ is appropriate for children ages 2-5 years and has shown good reliability and moderate correspondence with actigraphic recordings of child-sleep.[28, 29]
  - *Child Sleep Hygiene Questions:* Caregivers will report on child caffeine consumption, electronics in the bedroom, and noise in three questions drawn from our previous research.[23]
  - *Child Behavior Checklist (CBCL):* Caregivers will complete the 99-item Achenbach System of Empirically Based Assessment CBCL for children ages 1.5 to 5 years to report on child internalizing, externalizing, and attention problems.[30] The CBCL has shown strong reliability and validity in large validation studies and is a widely used measure of child behavior.[30]
  - *Center for Epidemiological Studies Depression Scale-Revised (CES-D-R):* Caregivers will report on their own depressed mood using the 10-item CES-D-R short form.[31-33] This indicator will be used as a control variable in study analyses. The CES-D-R has shown good reliability and validity in diverse adult samples.[31-33]

- *Connor-Davidson Resilience Scale 10 (CS-RISC-10):* Caregivers will complete the 10-item CS-RISC-10 scale[34, 35] to report on resilience, which may buffer the impact of child sleep concerns on caregiver mood. This indicator will be used as a control variable in study analyses. The CS-RISC-10 has shown good psychometric properties in community samples.[35]
- *Confusion, Hubbub, and Order Scale (CHAOS):* Caregivers will complete the 15-item CHAOS scale[36] to report on family organization and routines. This indicator will be used as a control variable in study analyses. The CHAOS scale has shown good psychometric properties in a diverse sample.[36]

- Measures during 14-day intervention period:
  - *Actigraph:* Objective child sleep will be assessed using a Philips Respironics, Inc., Actiwatch Spectrum,[37] which is a water-resistant accelerometer device. Consistent with guidelines for the reliable and valid use of actigraph devices in children,[38, 39] caregivers will be instructed to keep the actigraph on their child's ankle continuously for the 14-day study period, with the exception of bath time or swimming, to ensure that at least 10 days of data (to account for 4 days of missing data) are obtained.[38, 39] Caregivers will be asked to press an event marker at lights-off and lights-on. Actigraph data show an 85.1-88.6% agreement with polysomnography, which is the gold standard for objectively assessing sleep.[38, 39] Actigraph data will be analyzed using Philips Actiwatch software[37] and scored using guidelines for young children.[37] Actigraphs will generate daily total estimates of child nighttime sleep duration, bedtime, bedtime variability, sleep onset latency, and night wakings.
  - *Sleep Diary and sleep location:* Child sleep each night will be assessed via a diary as part of standard procedures for actigraphy validation.[38, 39] Fourteen questions related to child bedtime, wake time, sleep onset latency, night wakings, caregiver perception of child sleep quality, and child sleep location will be drawn from the BCSQ.[28, 29]
  - *Daily caregiver-reported child behavior*: Caregivers will report on daily child behavior using 5 items adapted from the CBCL and Brief Problem Monitor[40, 41].
  - *Daily self-reported caregiver mood and sleep:* Caregiver mood will be assessed using 3 items adapted from the Positive and Negative Affect Scale,[42] which has shown good reliability and validity in diverse adult samples.[42, 43] Caregiver sleep will be assessed using one item as assessed using one item drawn from the Pittsburgh Sleep Quality Index,[44] which has shown good psychometric properties.[44,45]

- Measures at 1-month follow-up:
  - *Brief Child Sleep Questionnaire (BCSQ):* Please see above for the BCSQ[28, 29] information.
  - *Child Behavior Checklist (CBCL):* Please see above for CBCL[30] information.
  - *Semi-Structured qualitative interview:* Please see the attached semi-structured interview protocol, which contains questions related to caregivers'

perceptions about sleep health and common behavioral sleep treatment approaches.

5.2 Efficacy Evaluations

5.2.1 Diagnostic Tests, Scales, Measures, etc.

The primary objective of this study is to evaluate the impact of provision of a child bed through the Beds for Kids program on objectively measured child sleep, and on daily child behavioral functioning, caregiver mood, and caregiver sleep over 14 days for preschool-aged children. The following measures will be used to determine the impact of bed prevision through the Beds for Kids program on child sleep, daily child behavior, and daily caregiver mood and sleep:

- Actigraph
- Caregiver-reported child sleep diary
- Caregiver-reported daily child behavior ratings
- Caregiver self-reported daily mood and sleep ratings

The first two of the secondary study objectives are to determine the impact of poor child sleep on daily child behavior, caregiver mood, and caregiver sleep, and to determine the impact of bed provision on child sleep at one-month follow-up. The following measures will be used for these objectives:

- Caregiver-reported child sleep at baseline and one-month follow-up
- Actigraph
- Caregiver-reported child sleep diary
- Caregiver-reported daily child behavior ratings
- Caregiver self-reported daily mood and sleep ratings

The final secondary study objective is to identify caregivers' perceptions of barriers and facilitators related to sleep health and common behavioral sleep treatment approaches (one-month post-bed delivery). The following measures will be used:

- Caregiver-reported qualitative interview

5.3 Pharmacokinetic Evaluation

Not applicable.

5.4 Safety Evaluation

Participant safety will be monitored by adverse events and examination of all validated child behavior (CBCL) and caregiver mood (CES-D-R) rating scales. Lead Investigator Dr. Ariel Williamson will review all questionnaires completed by families within 3 business days of completion in order to screen for clinically significant child behavior or caregiver mood concerns. In the event of clinically significant concerns Lead Investigator Dr. Ariel Williamson will contact the family by phone within 3 business days using the EMR for family contact information, to provide the family with appropriate community referrals for behavioral health services, as well as the information of the CHOP social workers employed at the primary care sites from which families are referred. For clinically significant ratings of caregiver depressed mood, Dr. Ariel Williamson will also further assess the caregiver for any safety risks (suicidal or homicidal ideation, plan, or intent). Should there be an imminent risk caregiver safety, we will contact emergency services (911 or Pennsylvania mobile crisis services) for further suicide/homicide/risk assessment. In the rare event that a participant necessitates psychological treatment due to adverse effects of study participation while completing study measures, the trained research assistant will contact Dr. Ariel Williamson by phone, and Dr. Williamson will speak with the participant, provide behavioral health resources, and screen for caregiver suicide/homicide risk in the manner described above. Although we are not asking caregivers to report on any instances of child abuse or neglect, should a caregiver spontaneously disclose this information to us during the study procedures or risk assessment we will file a Department of Human Services report in this regard, consistent with mandated reporting standards. All information obtained during the risk assessment will be used only for the purposes of determining appropriate follow-up care. Information about child-related safety screening and mandated reporting will be documented as a telephone encounter in the child's medical record, and will not be stored with study data, or used for any study-related data analysis. It will not be stated in the medical record documentation that the child or caregiver are participating in a research study. For caregiver risk assessment procedures, risk assessment will be documented in a Note to File coded by the participant ID and will be stored separately from the consent form and in a separate REDCap database used for tracking purposes only. Investigator and Licensed Psychologist Dr. Jodi Mindell and the Lead Investigator and Psychology Postdoctoral Fellow Dr. Ariel Williamson will meet weekly to monitor safety and will be in contact by phone during all data collection periods.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint is the change in objective and caregiver-reported child sleep.

6.2 Secondary Endpoints

Secondary endpoints will include the following:

- The association between child sleep and next-day child behavior (Aim 2)
- The association between child sleep and next-day caregiver mood (Aim 2)

- The association between child sleep and caregiver sleep (Aim 2)
- The change in child sleep based on caregiver report at baseline and one-month follow-up (Aim 3)

6.3 Statistical Methods

6.3.1 Baseline Data

Data for the primary objective and first two secondary objectives will be analyzed using Mplus Version 8.[46] Data will be summarized using descriptive statistics (means and percentages). We will examine the normality of the data and adjust analyses as needed.

6.3.2 Efficacy Analysis

The primary analysis will be based on an intention to treat approach and will include all randomized subjects. To evaluate the impact of provision of a child bed through the Beds for Kids program on child sleep (Hypothesis 1a), we will compare children in the study condition who received a bed at day 7 to those in the waitlist control condition (bed at day 14) on objectively and subjectively measured sleep variables using two-level multilevel mixed models. Multilevel models allow for an examination of both within-child (daily assessments, level 1) and between-child (level 2) associations between sleep and daily child and/or caregiver functioning.[20] Child age, sex, baseline caregiver mood and resilience, and family chaos as level 2 covariates, given research showing that these variables impact child sleep.[7, 9, 12] To examine whether children who receive a bed at day 7 show improved behavior, increased caregiver mood, and better caregiver sleep relative to children in the waitlist condition (Hypothesis 1b), we will run three different multilevel mixed effect models, using child daily behavior, caregiver mood, and caregiver sleep scores as the outcomes, respectively. Analyses will include child sleep location, age, sex, baseline caregiver mood and resilience, baseline family chaos, and baseline child internalizing and externalizing behavior at model level 2 as covariates.

Aim 2: To determine the impact of poor child sleep (short sleep duration, later bedtimes, inconsistent bedtimes, night wakings, and poor sleep quality) on *daily* child behavior and caregiver functioning (mood and sleep) (Hypothesis 2a), we will specify two-level multilevel models. We will use data from week 1 of the study, as at that time children in both conditions will not have received a bed through the Beds for Kids program. We will also specify models using 2-week data from those in the intervention group to assess whether improved sleep after week 1 as a result of receiving a bed also leads to improved functioning. In these models, each child sleep variable is entered as a predictor of each of the functional outcomes at level 1. Child behavior, caregiver mood, and caregiver sleep variables will be specified as outcomes in separate models. Covariates (as described for Aim 1) will be added to level 2. This multi-level modeling approach is consistent with other studies assessing associations between sleep and next-day child functioning.[20] To test whether the effects of poor sleep are cumulative (Hypothesis 2b), with children with poor sleep across multiple nights exhibiting the worst behavior, lowest caregiver mood scores, and worst caregiver sleep, we will run separate two-level multilevel models by outcome with averaged (cumulative) child sleep variables across week 1 nights as the predictors of

average child behavior, caregiver mood, and caregiver sleep ratings across this period. Child age, sex, baseline behavior, baseline family chaos, and baseline caregiver mood and resilience will be entered as level 2 covariates.

Aim 3: To determine whether provision of a child bed is associated with improved sleep health (longer nighttime sleep, earlier bedtimes, more consistent bedtimes, decreased night wakings, and better sleep quality) from baseline to one-month follow-up across study conditions (Hypothesis 3a), we will regress each follow-up sleep outcome on the baseline sleep outcome, with covariates including child age, child sex, study condition (to control for amount of time child has had the bed), and baseline caregiver mood and resilience, family chaos, and child behavior.

Aim 4: To identify caregivers' perceptions of barriers and facilitators related to sleep health and common behavioral sleep treatment approaches, we will use grounded theory approach that allows for relevant themes to emerge from the transcribed interview data. We will create a codebook using the first three interview transcripts to identify relevant themes. Once a stable codebook has been established, all transcripts will be coded using OSR NVivo© or ATLAS software. Once the coding is complete, we will examine each code to identify patterns in the data and key themes. We will integrate coded interview data with the quantitative study data above (i.e., caregivers' report of child sleep patterns and problems; actigraphy-derived data) to identify how barriers and facilitators may vary by child sleep habits.

6.4 Sample Size and Power

Based on power analysis[26] and a recent study of youth sleep and daily mood,[20] which detected a medium effect of nighttime sleep on daily mood, a total of 25 participants are needed across 14 days to detect medium (.35 to .45) daily effects of sleep on mood with 80% power and a p-value of <.05. To compare the two study groups (7-day and waitlist control) on the effects of Beds for Kids, 24 subjects (12 per group) are needed to detect an effect size of .45 with 80% power and a p-value of <.05, using repeated measures analysis of variance, 14 measures per subject, and a correlation of 0.5 among repeated measures. Our proposed sample of 50 caregiver-child dyads is thus sufficient, and will accommodate analyses for Aims 2 and 3.

A total of 5-10 qualitative interviews are needed to accommodate analyses for Aim 4. This sample size was based on semi-structured interview guidelines for qualitative research.[47]

6.5 Interim Analysis

There will not be an interim analysis as this study does not involve a life-threatening condition or a life-threatening outcome.

7 STUDY MEDICATION (STUDY DEVICE OR OTHER STUDY INTERVENTION)

7.1 Description

7.1.1 Packaging

The intervention for this study is involvement in the Beds for Kids program, through the non-profit organization One House at a Time (OHAAT). The program provides each child with a new twin mattress, a bedframe, and a "bedtime bag," which contains a sheet set, blanket, pillow, several books, stuffed animal, and toothbrush. Children also receive educational messages about healthy sleep habits (3 messages: bedtime before 9:00 PM; no caffeine; no electronics in the bedroom) via a magnet and "color-your-own" bookmark. In a previous study,[23] healthy sleep education was associated with increased nighttime sleep duration and fewer electronic items in the child's bedroom. All of the items are sorted, packaged, and delivered directly to program recipients by OHAAT members and volunteers.

7.1.2 Treatment Compliance and Adherence

Treatment compliance and adherence will be monitored by Lead Investigator Dr. Ariel Williamson through contact with the Beds for Kids program. However, no members of the Beds for Kids program will have access to any study data from participants. Dr. Williamson will monitor bed delivery scheduling and physical bed delivery in her capacity as Board Member of this organization.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review. Note that any AE related to the provision of the bed will be under the purview of Beds for Kids, and are not part of the procedures of this study.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

Participants will be randomly assigned by study statistician, Dr. Ji Young Kim, at a 1:1 ratio using code written into R statistical software. No stratification or blocking will be used.

9.1.2 Blinding

Families will not be blinded to condition assignment. The Lead Investigator Dr. Williamson, PI Dr. Mindell and Study Coordinator Mary Anne Cornaglia will not be blinded to condition assignment. However, all other members of the study team involved in data collection will be blinded to intervention group assignment. Blinding will be maintained by keeping a separate, password-protected list in REDCap that lists subject ID and group assignment. This database will be accessible only to the study statistician, PI (Dr. Mindell), Lead Investigator (Dr. Williamson), and Study Coordinator (Mary Anne Cornaglia).

9.1.3 Unblinding

As the Lead Investigator, Study Coordinator, and PI will not be blinded, and will review any adverse events, it is not necessary to unblind the other study team members during the conduct of the study.

9.2 Data Collection and Management

1. Confidentiality: Participants will be assigned a unique study ID number after consenting to study procedures. At this time, a member of the study team will record the child name in a separate, password-protected REDCap database that will be used as a master list linking child name, MRN, the contact information for the family, and study ID number, for EMR data abstraction purposes and for communicating with participants by phone for data collection and Beds for Kids bed delivery. A separate, password-protected and coded database will be used to store randomization

information, with only the study ID number and the results of randomization in the database. This database will be accessible only to the Lead Investigator Dr. Williamson and the PI Dr. Mindell. Participants will complete all survey measures in person, by entering responses electronically, or by phone, with a member of the study team, who will record responses electronically. All survey responses will be recorded electronically into a separate, coded REDCap database that is password-protected and accessible only to members of the study team. This REDCap database only contains subject ID numbers and questionnaire responses. To complete the baseline Child Behavior Checklist (child internalizing and externalizing behavior questionnaire) a member of the study team will enter the child unique study ID number and child chronological age into a separate, password-protected CBCL portal accessible only to the study team members. Because of copyright protections, the CBCL measure cannot be reproduced on the REDCap platform, but can be accessed through a secure, HIPAA-compliant web portal. This portal is found at: https://www.aseba-web.org/SignIn?ReturnUrl=%2f. No identifying participant information will be entered in this portal. Only unique study ID, child age (for scoring purposes), and caregiver responses will be entered. The privacy policy for the Child Behavior Checklist portal can be found here: http://www.aseba.org/aboutus/privacy.html. A member of the study team will also review the participating child's EMR to abstract child age, sex, race, ethnicity, BMI, current medications and diagnoses, and zipcode, which will be stored in a separate, coded REDCap database with participants identified only by unique study ID.

For the qualitative interview data, participants' responses will be audio-recorded in person. The audio-recording devices will be password protected. The audio files will also be password-protected and temporarily saved on Dr. Ariel Williamson's password-protected research drive on a password-protected computer. Transfer of audio files from the password-protected audio device to the Lead Investigator's computer will occur via a flash drive that is encrypted and password-protected per CHOP IT standards. Once the audio file is transferred from the audio-recording device, it will be deleted from the flash drive and from the audio-recording device. In the drive on the password-protected computer, audio files will be labeled according to participants' unique study ID numbers, and no identifying information will be used to label the files. Audio files will then be transcribed, at which point the digital files will be destroyed. Transcribed interview data will be coded using participants' unique study ID numbers. Any interviewer field notes taken during the interview will be coded using only the participants' unique study ID numbers, and stored in Dr. Ariel Williamson's locked cabinet in her CHOP office until the point of transcription. Audio recordings may be sent to an outside professional transcription agency, ACTS Document Management located in South Point, Ohio. All files are securely stored, transmitted, and encrypted. The agency will remove all identifying information from the transcripts and destroy their copy of the audio files after transcription is complete. Interviewer field notes will then be destroyed. The transcribed interview and interviewer field note data will be stored in password-protected files on the Lead Investigator's office computer.

2. Security: Copies of only coded data (i.e., with participant unique study ID, demographic information, questionnaire responses, the transcribed interview and interviewer field note data, and the database with randomization information) will be downloaded from the REDCap and the CBCL electronic platform for data analysis purposes. These data will be stored in password-protected files on the on the Lead Investigator's office computer, in a research secure server. The separate, password-protected REDCap dataset that contains the master list linking the child name, MRN, and unique study ID number will not be downloaded, and will only be accessible on the secure, password-protected REDCap server. As noted above, for audio files, transfer of files from the password-protected audio device to the password-protected computer will occur via an encrypted and password-protected CHOP flash drive, consistent with CHOP IT security procedures. Uploads of audio files to the ACTS Document Management site for transcription purposes will also be encrypted. ACTS Document Management has been vetted by CHOP and is compliant with all CHOP technology transfer policies.

3. Anonymization: All identifiers (child name, contact information and MRN) that are stored in the separate, password protected REDCap database master list will be retained for 6 years and then destroyed, consistent with CHOP Hospital Policy. The de-identified data will be retained indefinitely through password-protected files on the secure research server, on the CBCL portal, and on the REDCap platform.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the PI, Lead Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes). If families encounter any difficulty with materials provided to them through Beds for Kids (i.e., mattress, bedframe), the family will be asked to contact Beds for Kids staff directly. We will not disclose any study data or family identifying information to the Beds for Kids program.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

The Principal Investigator Dr. Jodi Mindell will maintain oversight over data integrity and subject safety. Participants will complete all study measures by phone with a member of the study team electronically recording participant responses. To maintain data integrity and safety, survey data will be recorded into separate, coded REDCap databases that are password-protected. Transcribed interview and interviewer field note data will be stored in separate, password-protected files. Audio files will be deleted from the audio-recording device and from the encrypted and password-protected flash drive (see section 9.2, above)

once they are transferred to the Lead Investigator's password-protected computer. The audio files will be temporarily stored on the Lead Investigator's password-protected computer, on a secure research server, until they are transcribed, at which point they will be destroyed. One coded REDCap database, which is accessible to all members of the study team, only contains subject ID numbers and questionnaire responses. Another coded REDCap database, which is accessible only to Dr. Mindell and Lead Investigator Dr. Williamson, contains randomization information and subject ID numbers. As described above in section 9.2, a separate, password-protected REDCap database will contain the master list linking the unique participant study ID to participant names, contact information, and MRN. Data will be stored in password-protected files on the on the Lead Investigator's office computer, in a research secure server. The separate, password-protected REDCap dataset that contains the master list linking the child name, contact information, MRN, and unique study ID number will not be downloaded, and will only be accessible on the secure, password-protected REDCap server. No individual from the Beds for Kids organization will have access to any study data.

To maintain patient safety, validated questionnaires of child behavior (CBCL) and caregiver mood (CES-D-R) will be scored and reviewed by Lead Investigator Dr. Ariel Williamson within 3 business days of measure completion. In the event of clinically significant child behavior or caregiver mood concerns Dr. Ariel Williamson will contact the family to provide the family with appropriate community referrals for behavioral health services, as well as the information of the CHOP social workers employed at the primary care site from which the family was referred. If caregivers report clinically significant depressed mood, Dr. Ariel Williamson will also complete a suicide/homicide risk assessment by phone. This risk assessment will contain questions about caregiver homicidal and suicidal ideation, and the presence of any homicide/suicide plan or intent, consistent with CHOP behavioral health risk assessment practices. Should there be an imminent risk to caregiver safety, Dr. Williamson will contact emergency services (911 or Pennsylvania mobile crisis services) for further suicide/homicide/risk assessment.

In the rare event that a participant necessitates psychological treatment due to adverse effects of study participation while completing study measures by phone, or at any point during the study, Dr. Williamson will speak with the participant, provide behavioral health resources, and screen for caregiver suicide/homicide risk in the manner described above. Although we are not asking caregivers to report on any instances of child abuse or neglect, should a caregiver spontaneously disclose this information to us during the study procedures or during the risk assessment phone call, we will file a Department of Human Services report in this regard. Based on standard behavioral health practices within the CHOP system, these procedures are likely to be effective in the case that additional behavioral health treatment and/or risk assessment are necessary. Investigator and Licensed Psychologist Dr. Jodi Mindell and the Lead Investigator and Psychology Postdoctoral Fellow Dr. Ariel Williamson will meet weekly to monitor safety and will be in contact by phone during all data collection periods. In addition, Dr. Mindell and Dr. Williamson are experienced in talking with families who are under stress due to child behavior concerns, parent mood concerns, or contextual issues (e.g., poverty, housing instability). Members of the study team will also offer participants an opportunity to reflect on their experience (i.e., 'debrief')

after study measure completion. Monthly, Drs. Mindell and Williamson will check in with the executive director of the Beds for Kids program, , who will not have access to any data, regarding any study concerns reported to the Beds for Kids staff.

All information obtained during any of the study-related risk assessments described above will be used only for the purposes of determining appropriate follow-up care. This information will not be stored with study data, or used for any study-related data analysis. It will not be stated in the medical record documentation that the child or caregiver are participating in a research study.

9.4.2 Risk Assessment

Study participation poses minimal risks to subjects. Completion of child sleep, behavior, and caregiver mood survey instruments as part of this study does not confer greater than minimal risks for participants. There are minimal risks related to confidentiality and breach of privacy in collecting these instruments from participants. These risks will be addressed through maintaining coded REDCap databases and a separate REDCap database with the subject IDs and identifying information (e.g., MRNs); for further information please see the plan for safeguarding these data, described above in section 9.2, above.

Completing survey instruments or answering interview questions could also be potentially stressful or anxiety-provoking, or could identify the presence of clinically significant child behavior or caregiver mood concerns that warrant treatment. These risks will be addressed by scoring survey instruments within 3 business days of measure completion, and, in the case of clinically significant child or caregiver scores, contacting the family to provide appropriate referrals for treatment, to engage in further suicide/homicide risk assessment screening for clinically significant caregiver mood concerns, and to refer caregivers to emergency services if warranted in the case of imminent risk, as described above in section 9.4.1, above. We will also offer participants an opportunity to reflect on their experience (i.e., 'debrief') after study measure completion.

9.4.3 Potential Benefits of Trial Participation

Direct benefits: All participants in the study will participate in the Beds for Kids program, which has been found to benefit caregiver-reported child sleep in a previous study. Thus, children in this study may benefit from provision of a bed and sleep education through the Beds for Kids program.

More broadly, families who seek treatment at the CHOP primary care study sites may also benefit, as beds through Beds for Kids have been reserved for this study.

Indirect benefits: The results of this study will help us to better understand the sleep patterns of lower-SES children, and to determine whether bed provision positively impacts objectively-measured child sleep, daily child behavior, and caregiver functioning (mood and sleep).

9.4.4 Risk-Benefit Assessment

This study will provide information about the sleep patterns of lower-SES preschoolers, and will also provide information about whether bed provision and sleep hygiene through the

Beds for Kids program can benefit child sleep and daily child behavior and caregiver functioning (mood and sleep). This information, in turn, could help to inform dissemination of the Beds for Kids program or methods, which would help to ameliorate risk for sleep concerns in lower-SES children. The benefits of this study outweigh the minimal participant risks associated with study procedures.

9.5 Recruitment Strategy

Participants will be recruited from the Chestnut Hill, South Philadelphia, Karabots, and Cobbs Creek CHOP primary care offices. The providers at each of these care sites, who are already partners with the Beds for Kids program and make program referrals, will be informed of this study. If the subjects are interested in the study, the CHOP clinician will provide the study team with the child's name, MRN, and contact information. To assist providers in identifying potentially eligible subjects, we will provider them with a flyer summarizing recruitment and study information. Given that the CHOP primary care sites conduct approximately 233,757 visits per year, we believe that we will be able to recruit a sufficient number of participants to meet the goals for this objective. In addition, this recruitment strategy has been discussed with the providers at each of the primary care sites for this study, and has been approved by the Pediatric Research Consortium.

In addition, families receiving care at any of the CHOP primary care recruitment sites (Chestnut Hill, South Philadelphia, Karabots, or Cobbs Creek) may self-refer to the study if they hear of the Beds for Kids program through word-of-mouth or social media (e.g., Facebook). However, we will not advertise the study on social media of any kind for recruitment purposes.

9.6 Informed Consent/Assent and HIPAA Authorization

A member of the study team will be responsible for obtaining informed consent. Informed consent will be obtained from the child participant's legal guardian; child assent will not be obtained as all children are under age 5 (please see section 8.6.2 for further information). We are requested a waiver of documentation of consent and an alternation of HIPAA Authorization as we will be obtaining verbal consent from subjects by phone for study participation and for HIPAA authorization. Participants will be given unlimited time to decide their participation. Families will be informed of the nature of this research, study procedures, and its potential benefits and possible risks. Families will be informed that they are free to decline to participate or to withdraw from the study, and that this will not impact any future medical care or their likelihood of receiving a bed through Beds for Kids. Families will be asked to explain back to the investigators the nature of the study, study procedures, and risk and benefits of participants to assure their understanding. A combined consent-authorization document will be used. A copy of the completed verbal consent form will be provided to participants for their records.

When called to schedule study follow-up by a member of the study team, participants will be given the opportunity to schedule to provide written, in-person consent for and to complete a qualitative interview (Study Aim 4). Consistent with the initial informed consent, this consent will be obtained from the child participant's legal guardian, and child assent will not be obtained due to the child's age. Participants will be given unlimited time to

decide their participation. Families will be informed of the nature of this research, study procedures, and its potential benefits and possible risks. Families will be informed that they are free to decline to participate or to withdraw from the study and that this will not impact any future medical care. Families will be asked to explain back to the investigators the nature of the study, study procedures, and risk and benefits of participants to assure their understanding. A copy of the completed written consent form will be provided to participants for their records.

9.6.1 Waiver of Consent

Not applicable. As described above in section 9.6, we are requesting a waiver of documentation of consent for the study procedures related to Study Aims 1 through 3. Written consent for Study Aim 4 (qualitative interview) will occur in person.

9.6.2 Waiver of Assent

A waiver of assent is requested as all child participants will be between the ages of 2 and 5 years. The capacity of children in this age group is so limited that they cannot reasonably be consulted about their assent and study participation.

9.6.3 Waiver of HIPAA Authorization

Not applicable. We are requested an alternation of HIPAA authorization as we will be obtaining HIPAA authorization from subjects by phone.

9.7 Payment to Subjects/Families

9.7.1 Reimbursement for travel, parking and meals

Not applicable.

9.7.2 Payments to parent for time and inconvenience (i.e. compensation)

Not applicable.

9.7.3 Payments to subject for time, effort and inconvenience (i.e. compensation)

The compensation for study participation will be as follows:

- The parent/caregiver assessment will receive $25.00 cash for questionnaire completion at baseline.
- The caregiver of the participating child will receive $4.00 for each day that the caregiver completes the sleep diary and the child wears the actigraph over the 14-day measurement period (14 days x $4.00 = $56.00 total)
- The caregiver of the participating child will receive $4.00 for each day that the parent completes the 14-day measurement period (14 days x $4.00 = $56.00 total)
- The caregiver of the participating child will receive $8.00 for having complete data (i.e., all measurement occasions complete) over the 14-day daily measure period.
- The caregiver of the participating child will receive $25.00 for questionnaire completion at one-month follow-up.

- The caregiver of the participating child will receive $20.00 for interview completion at one-month follow-up.

For the daily measures, providing subjects with daily incentives and additional compensation for complete data has been shown to increase measure adherence to ≥ 94%.[20]

9.7.4 Gifts

Not applicable.

10 PUBLICATION

We intend to present the results of this project at national conferences and to publish project results in peer-reviewed journals.

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