PROTOCOL

STUDY INFORMATION

Title of Project: Sleep in Adolescents- Pilot

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Table of Contents

1.0	**Research Design**
1.1	Purpose/Specific Aims
1.2	Research Significance
1.3	Research Design and Methods
1.4	Preliminary Data
1.5	Sample Size Justification
1.6	Study Variables
1.7	Specimen Collection As A Primary Source
1.8	Interviews, Focus Groups, or Surveys and/or Observations
2.0	**Project Management**
2.1	Research Staff and Qualifications
2.2	Resources Available
2.3	Research Sites
3.0	**Multi-Site Research Communication & Coordination**
3.1	Non-Rutgers Research Sites
4.0	**Research Data Source/s**
4.1	Primary Data – Subjects and Specimens
4.2	Subject Selection and Enrollment Considerations
4.3	Subject Randomization
4.4	Secondary Subjects
4.5	Number of Subjects
4.6	Consent Procedures
4.7	Special Consent Populations
4.8	Economic Burden and/or Compensation
4.9	Risks and Benefits to Subjects
4.10	Secondary Data – Record/Chart Reviews, Databases, Tissue Banks, Etc.
4.11	Chart/Record Review Selection
4.12	Secondary Specimen Collection
5.0	**Special Considerations**
5.1	Health Insurance Portability and Accountability Act (HIPAA)
5.2	Family Educational Rights and Privacy Act (FERPA)
5.3	NJ Access to Medical Research Act
5.4	Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
6.0	**Research Data Protection and Reporting**
6.1	Data Management and Confidentiality
6.2	Data Security
6.3	Data and Safety Monitoring
6.4	Reporting Results
6.5	Data Sharing
7.0	**Data and/or Specimen Banking**
8.0	**Other Approvals/Authorizations**
9.0	**Bibliography**

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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of this proposed pilot study is to test different recruitment approaches, examine the acceptability and feasibility of 3h sleep extension in 14-17 year olds, and determine if there are any issues with having adolescents wear the two devices we use to measure sleep and physical activity.

A. Objectives

The proposed study will serve as a pilot for a planned future study. In the future study, adolescents will be asked to increase time-in-bed (TIB) for sleep by ~3h/night in order to assess how sleep extension impacts markers of insulin sensitivity.

B. Research Question(s)

Aim 1: Determine the additional amount of sleep short-sleeping-adolescents (~7h TIB/night) will obtain when asked to increase time-in-bed to 10h/night for seven consecutive nights compared to those who are not asked to increase time-in-bed.
Aim 2: Determine if adolescents are able to comply with study demands: wearing two devices (one on wrist and one on hip) and completing daily sleep diaries and call-ins for seven days.
Aim 3: Acquire participant feedback regarding feasibility and acceptability of increasing TIB for sleep to 10h/night using a questionnaire and semi-structured interview.

1.2 Research Significance

Short sleep has become a significant health concern in adolescents; approximately 73% of adolescents in the U.S. self-report sleeping less than the recommended 8-10 h/night (1), and many exhibit irregular sleep patterns with short sleep during school nights and longer sleep on weekends (2). Observational studies reliably demonstrate a relationship between adolescent short sleep and adverse health outcomes (3-5). Therefore sleep interventions that successfully increase sleep duration are needed in this age group. Furthermore, adolescence may represent an important stage in the lifespan to target a sleep intervention as it is a developmental period during which lifestyle patterns – such as sleep, eating, and activity behaviors– are established and endure into adulthood(6). It is critical to first assess the feasibility and acceptability of increasing sleep duration in short sleeping adolescents prior to conducting a larger experimental study which will examine the impact of increased sleep on metabolic health outcomes.

1.3 Research Design and Methods

Adolescents (14-17y) will be recruited to participate in an observational pilot study. Participants will be asked to wear a sleep monitor on the wrist, a physical activity monitor on the hip, and complete a brief daily sleep diary and call-in procedure for 1 week. Approximately 15 subjects will be assigned to increase their time-in-bed for sleep by ~3h per night and 15 subjects will maintain their normal sleep schedule. The proposed study will incorporate a mixed-methods approach to gather information about the feasibility of implementing a similar sleep protocol in a future study.

A. *Screening Interview:* Participants will undergo a phone screen which will be carried out by the trained study coordinator or a research assistant. During the phone screen, participants will be asked to provide oral consent so information can be recorded to determine participant eligibility. If participants are determined to be eligible, they will be invited by the study staff to the sleep center for an orientation to the study. Prior to scheduling families, research staff will ensure that there are no planned family vacations, changes in typical family routine that might impact sleep (e.g., planned sleepovers), or current minor illness(e.g., colds) that might disrupt sleep or result in the child needing to take medications that might impact sleep. The study will be timed around family's schedules to maximize adherence to study protocol. Subjects who expressed interest to participate in future research studies will be screened again to determine eligibility following modification Mod2018002469 to the study protocol. Only subjects who gave permission to be contacted again will be screened again.

Orientation: When the family arrives to the sleep center, study staff will first collect additional eligibility information (height and weight measurement, additional information about the adolescent's typical sleep, availability to complete study

schedule). Note: if the subject is not eligible based on BMI, the height and weight data will be destroyed immediately. If the adolescent is eligible, study staff will provide an overview of the study and will review the Informed Consent/Assent forms with the family.

Participants will be asked to provide written informed consent/assent prior to data collection. After participants agree to participate and are enrolled in the study, participants will complete the followingquestionnaires: 1) Children's Chronotype Questionnaire (7), 2) Demographic Questionnaire, 3) Sleep Disorders Inventory for Students- Adolescents (SDIS-A) (8) 4) Mood Questionnaire (9), the Perceived Stress Scale (10) and the Freiburg Mindfulness Inventory (11) (NOTE: questionnaires will be converted to an online format using Qualtrics, an online survey platform). Participants will also complete a battery of cognitive tests during the orientation to assess how sleep affects cognitive function (12). A final check for eligibility (based on the sleep disorder questionnaire) will be conducted. Adolescents who remain eligible will be provided with wrist actigraphs, waist accelerometers and sleep diaries and instructed on their use for the next 7 days. To assist in scoring the actigraphs, participants will be asked to call a time-stamped voice mail (or text) twice daily: before bedtime and when they wake up. Research staff will follow up with families who do not call in or text.

A consistent wake time will be established with families randomized to the 10 h time-in-bed condition based on the adolescents' typical schedules. Bedtime will then be calculated as 10 h prior to wake time. Families will be provided with handouts (See Tasks Overview for Families) that explicitly state the participant's bedtime and wake time for each day during the sleep schedule to ensure adherence to the protocol. Research staff will also discuss the participant's bedtime routine and will ask that participants begin that routine with the sufficient time so that it can be completed prior to the prescribed bedtime. Research staff will reiterate that the participant must be lying in bed with the lights out at the prescribed bedtime, and that an alarm clock should be set for the prescribed wake time. Parents will also be asked to ensure that the adolescent goes to bed and wakes up (and gets out of bed) on time. Participants will be instructed to remain in bed with the lights off even if they have difficulty falling asleep or wake up earlier than the prescribed wake time. Participants must refrain from engaging in any activity (e.g., reading a book or engaging in social media) during the prescribed TIB.

Handouts (See Sleep Health Education Information Sheet) on sleep hygiene practices (i.e., strategies to ensure a good night's sleep) will be reviewed and provided to families. These include a list of caffeinated foods/beverages to avoid after 2pm, not watching TV, using computer/smartphone/tablet or play video games as part of the bedtime routine, and ensuring that the adolescent has a quiet, cool, and dark sleep environment. Research staff will discuss potential barriers to following the protocol and provide strategies to overcome these barriers (e.g., providing participants with an eye mask to block out excess light, discussing the use of fans or white noise machines to decrease noise, turning phone/tablets off or giving these devices to parents when it is time for bed and recording TV shows that begin late at night).

Subjects who are randomized to the control condition will be asked to maintain their typical bedtime and wake times. These subjects will be instructed to wear wrist actigraphs, waist accelerometers, complete sleep diaries and call-ins for 7 days. Handouts and resources on sleep hygiene practices will be reviewed at the end of the study.

Study staff will conclude the orientation session by answering any remaining questions that the family has and scheduling the follow-up visit.

Week-long study protocol: Participants are instructed to wear the sleep monitor (on wrist) 24h a day for the entire 7 day period and to wear the physical activity monitor (on hip) during all waking hours for the entire 7 day period. Participants will be given a 7-day sleep diary to complete daily. This provides an additional monitor of sleep which assists in analysis of wrist actigraph data and serves as an effective behavioral strategy to increase adherence to the protocol via self-monitoring. Participants will also be asked to call in twice daily (just prior to bedtime and upon waking in the morning) to a time-stamped voice mail box or send a text to the study's Google voice account. If a family fails to call in/text or calls in bed bed/wake times are outside prescribed times, research staff will follow-up with families by phone to ensure protocol adherence. Research staff will also maintain a rolling calculation of adherence to the sleep schedule for subjects asked to complete 10h TIB.

Follow-Up Visit: The participant and his/her parent will return to the sleep center approximately 1 week after the orientation to return the wrist actigraph, waist accelerometer and sleep diary. Study staff will administer an accelerometer question form and an actigraph question form to inquire about any discrepancies in recorded diary entries, actigraphy data and call-in log information. This will take place in the form of a semi-structured interview. Additionally, participants will be asked to repeat the mood questionnaires, Perceived Stress Scale and the Freiburg Mindfulness Inventory (11)complete an exit-survey (Acceptability/Feasibility Questionnaire) and semi-structured interview related to their overall impressions of the study to gain more information about study feasibility. The cognitive battery will be administered again for assessment of cognitive function after prescribed bed-time (12)/control condition. Participants will be provided $10 for each 24-hour period that they follow study procedures. Specifically, each night that they call/text prior to getting into bed, get into bed at their prescribed bedtime (i.e., the actigraph is consistent with the reported bedtime), call/text in the morning right when they wake and get out of bed at the prescribed wake time (i.e. the actigraph is consistent with the reported wake time), the participant will earn $10 (total possible: $70). Our research team has found that this strategy results in very high adherence to experimental sleep protocols.

B. Participants will be asked to participate in a phone-screening interview (15-20 minutes). If initially determined eligible by the phone screen, participants will be invited to visit the sleep center for a study orientation (1.5-2 hours). During the orientation, informed consent will be obtained (10-20 minutes). Participants will be asked to wear a wrist actigraph and waist accelerometer for the week following orientation (1 week). Participants will be expected to wear devices during the entire week as well as call a time-stamped voicemail during wake and bed times and complete sleep diaries daily. Participants will be asked to report to the study center approximately one week after the orientation date for a follow-up visit (1-1.5 hours) to deliver devices, undergo a semi-structured interview about the sleep data that was collected, and provide study staff with feedback regarding the study.

1.4 Preliminary Data

N/A: Adherence to changes in sleep duration as prescribed in a sleep protocol has not been studied in adolescents.

1.5 Sample Size Justification

The proposed study's purpose is to serve as a pilot study to gain exploratory data on approximately 30 adolescents to explore sleep health study feasibility in New Brunswick, New Jersey. Therefore, power analysis was not performed.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The proposed study is a pilot to assess the feasibility of increasing adolescent time-in-bed for sleep to 10 h/night for seven consecutive nights. Individuals who regularly sleep 7h/night will be recruited to participate in the research study. A sleep protocol will be implemented to either increase individual sleep by ~3 h/night or maintain a typical sleep schedule. Study staff will work with the participants to determine a bedtime wake time schedule that will increase number of hours from 7h/night to 10h/night. The purpose of this research is to gain new information about sleep study feasibility.

B. Dependent Variables or Outcome Measures

Sleep: Sleep will be monitored using the Actiwatch Spectrum Plus (Phillips Respironics, Murrysville, PA). Wrist actigraphy is a widely used, reliable and valid approach for measuring sleep (13-15). The device is worn on the non-dominant wrist across the 24-hour period and monitors motor activity to obtain continuous recordings of sleep-wake states. In this study, the device will be configured to store data in a 1-minute epoch in accordance with pediatric reliability and validity studies (13, 16). Epochs are scored as sleep or wake by Actiware 6.0 software using an algorithm that modifies activity counts during a single epoch by activity produced in the surrounding two minute time period (16). **The primary variable of interest is the actigraph**

measured sleep period, which is the period between actigraph-estimated sleep onset and wake. Participants will be asked to press a button on the device when they go to bed and once when they wake up. Additionally, daily call-ins will provide an additional measure of bedtime and waketime and daily sleep diaries will be used to collect participants' estimate of bedtime and wake time, awakenings during the night, and daytime sleep (i.e. naps). This information is critical for verifying and scoring actigraphy data and provides an additional measure of sleep duration.

Physical activity: Physical activity will be tracked using the Actigraph GT3X (ActiGraph Corp, Pensacola, FL). Hip-worn accelerometry is a reliable and valid objective assessment of physical activity in adolescents (17, 18). Participants will be instructed on how to wear the device (device placement, only to wear during waking hours, whether the device can be worn in water etc.). Standard procedures for scoring (i.e. number of valid days, minimum amount of daily wear time needed and detection of non-wear time) and an established algorithm for determining the amount of time spent in moderate/vigorous activity will be used (17). **For this pilot study, the primary variable of interest is daily wear time.**

Acceptability/Feasibility: The acceptability and feasibility of increasing time in bed for sleep to 10h/night will be assessed with a questionnaire and a semi-structured interview to follow up on participant questionnaire responses. Of interest will be the participant's perceptions of **1) how challenging obtaining more sleep is during school nights is, 2) benefits they experienced as a result of sufficient sleep; and 3) what type of messaging and strategies should be used in a future sleep intervention**. These responses will guide future studies examining the effect of sleep extension on metabolic health and aid in the development of sleep intervention in adolescents. The research team has successfully used this multi-method approach in previous studies. Research staff will also maintain a rolling calculation of adherence to time-in-bed with sufficient adherence defined as ≥85% of the prescribed time-in-bed.

1.7 Specimen Collection as a Primary Source

N/A

1.8 Interviews, Focus Groups, Surveys, and/or Observations

A. Administration

At the follow-up study visit, participants will complete a semi-structured interview with study staff to go over the previous week's sleep data. Specifically, study staff will download the sleep actigraph data and print out a summary of the actigraph-determined periods of sleep, rest, and wake as well as anytime the device was considered to be "off-wrist". Study staff will compare this data with sleep diary responses and call-in information. Any discrepancies will be reviewed with the participant and off-wrist periods will be confirmed or explained. Similarly, study staff will review wear the hip-worn device data to determine when the device was taken off, and reasons for being off. In addition, participants will complete a feasibility/acceptability questionnaire and then undergo a semi-structured interview with study staff to follow up on the responses in order to inquire about the participant's overall study experience and gain more information about sleep in adolescents to inform future studies. Study staff (study coordinator and research assistant) will be responsible for administering questionnaires and the PI will oversee all operations.

- **Timing and Frequency**

Semi-structured interview regarding device data will occur at the follow-up visit, and is expected to last approximately 30-45 minutes.
Feasibility/acceptability questionnaire and follow-up interview will also occur during the follow-up visit and is expected to take approximately 10-15 minutes.

- **Location**

A closed-door office space will be used to ensure participant confidentiality and privacy in Loree Classroom Building on Rutgers Cook/Douglass campus.

- **Procedures For Audio And Visual Recording**

N/A

- **Person Identifiers**

Subjects will be asked for their name and phone number for scheduling/recruitment purposes only. The study coordinator and PI will be the only research staff members that have access to person identifiers during the entire duration of the study. Participant person identifiers will be stored in a separate location from any study-related data. During the informed consent process, we will ask subjects and their parent(s) if they would like to be contacted in the future to be recruited for additional sleep studies. A separate section and checkbox will be included on the Parental Informed Consent form. Identifiable information will be stored in a separate database from the experimental data. Subject ID numbers will be assigned and used for data collection and analysis. For those who do not consent to be contacted in future studies, identifiers will be destroyed after completion of the study, or, in the event a participant does not continue with the study, after withdrawal from study participation.

B. Study Instruments

Note: Study instruments will be converted to an online format using the Qualtrics survey platform. Supporting documents can be found in the eIRB submission

- **Anthropometrics:** At the orientation, participant's height (wall-mounted stadiometer, measured in duplicate) and weight (digital scale, measured in duplicate) will be measured using standard procedures (participant wearing street clothes, without shoes). Theses measure will be converted to BMIz and BMI percentile using age and sex-adjusted normative data from the CDC(18).

- **Demographic Questionnaire:** At the orientation, participants (with assistance of parents as necessary) will complete a demographic questionnaire which will include the following information: participant age, gender and racial and ethnic group, parent education and occupational status.

- **Child Chronotype Questionnaire**: At the orientation, participants will complete this questionnaire (7) in order to determine his/her chronotype. In adolescents, evidence suggests that chronotype, an individual's preference for activity early (morning-type, "lark") versus late (evening-type, "owl") in the day, affects sleep, diet and weight status (19, 20) which will be important information for planning the future metabolic health study.

- **Sleep Disorders Inventory for Students-Adolescents (SDIS-A):** At the orientation information obtained from this questionnaire (8) will determine if the adolescent is eligible for participation in the study. If a participant's score indicates that he/she may be at risk for a sleep disorder, the family will be referred to the Robert Wood Johnson Sleep Clinic, and the adolescent will not be eligible to participate in the study.

- **Mood questionnaire:** The Profile of Mood States Second Edition (POMS 2) instruments assess the mood states of individuals 13 years of age and older. The instrument is a self-report scale that allows for the quick assessment of transient, fluctuating feelings and enduring affect states(9).

- **Perceived Stress Scale:** The Perceived Stress Scale (PSS) measures the degree to which situations in one's life are considered stressful (10, 21). Previously, the PSS was designed for use in a population with at least a junior high school education. The questions are general in nature and easy to understand.

- **Freiburg Mindfulness Inventory:** The Freiburg Mindfulness Inventory (FMI) is a consistent and reliable scale used to measure mindfulness, and it has previously been validated for use in research and clinical applications to appropriately measure mindfulness(11, 22).

- **Actiwatch Spectrum Plus (Phillips Respironics, Murrysville, PA):** During the week between the orientation and follow-up visits, participants will wear the device on their non-dominant wrist across the 24-hour period. The device monitors motor activity to obtain continuous recordings of sleep-wake states (See Actiwatch and Accelerometer Information attachment for picture and spec sheet).

- **Sleep Diary:** During the week between the orientation and follow-up visits, participants will complete entries in a brief sleep diary daily. This provides a participant's estimate of bedtime and wake time, awakenings during the night, and daytime sleep (i.e. naps).

- **Actigraph GT3X (ActiGraph Corp, Pensacola, FL):** During the week between the orientation and follow-up visits, participants will wear the device (which is on a belt) on their right hip during waking hours. Motor activity is obtained in order to determine how much time the participant spends in sedentary, moderate and vigorous activity (See Actiwatch and Accelerometer Information attachment for picture and spec sheet).

- **Acceptability/Feasibility Questionnaire:** At the follow-up visit, participants will complete a brief questionnaire asking about their experience with the research study. Study staff will then conduct a semi-structured interview with the participant to follow-up on their responses.

- **Battery of Cognitive Tests via Joggle Research Application:** During the initial and follow-up visit a battery of cognitive tests will be administered to participants using Joggle, which is an iPad application(12). The first test is Motor Praxis Task (MPT), where boxes pop up in different places across the screen and will only disappear when tapped. Next is Visual Object Learning Task (VOLT), where participants are shown a set of shapes, and need to be able to recall the previous shapes when they are mixed in with new shapes. The NBACK test is a test where images are shown in a certain order and the participant needs to be able to pick an image that they had seen a certain number of screens before. Abstract Matching (AM) is a test where participants are shown a single shape, and 2 pairs of shapes, and needs to choose which pair fits the original shape. Line Orientation Test (LOT) is a test where participants need to rotate a line using the shortest path, so it will be parallel with another line. Digital Symbol Substitution Task is where participants are shown a list of numbers that correspond to symbols, and when they are shown a single symbol, they need to select the corresponding number. Balloon Analog Risk Task (BART) is a test where participants need to inflate the balloon on the screen to maximize the reward, but will receive nothing if the balloon pops. The last test is the Psychomotor Vigilance Test (PVT), participants are shown random stimuli and cannot respond early. The total battery will take approximately 20 minutes to complete and will be performed in a closed-door office space with minimal distraction. Trained research staff will be present to answer questions about the application.

2.0 Project Management

2.1 Research Staff and Qualifications

Principal Investigator: Andrea Spaeth, Ph.D. is a tenure-track Assistant Professor in the Department of Kinesiology and Health at Rutgers University. Dr. Spaeth has been conducting sleep research for the past 6 years and has professional training in monitoring sleep using actigraphy, tracking physical activity using accelerometry and conducting experimental sleep research.

Study Coordinator: Taylor McCoy has over 2 years experience working in human subject research. She has experience using the equipment in this protocol and in obtaining informed consent and conducting experimental study procedures.

2.2 Resources Available

A. Facilities
Orientation and follow-up visits will be held at an office on the Cook/Douglass campus of Rutgers University. A closed-door office space will be used to screen participants for eligibility and describe study related procedures.

B. Medical or Psychological Resources
Participants will be asked to complete a sleep disorders questionnaire. In the event a participant achieves a score that excludes them from the study, we will provide the participant with a referral to the Robert Wood Johnson Sleep Clinic.

C. Research Staff Training
All members of the study staff will undergo mandatory clinical research IRB training as requested by Rutgers University. The study coordinator will be trained in informed consent/assent, protocol and research related procedures prior to the initiation of study-related tasks. Ongoing training will be administered to ensure that the study coordinator is competent in his/her duties and functions. Research assistants will be trained by the study coordinator and all trainings will be documented to ensure the appropriate trainings are delivered to staff persons working on study procedures.

2.3 Research Sites

1) *Rutgers Sleep Lab*
Department of Kinesiology and Health, Rutgers
The State University of New Jersey
Loree Classroom Building Office 018
72 Lipman Drive
New Brunswick, NJ 08901

3.0 Multi-Site Research Communication & Coordination

N/A

3.1 Non-Rutgers Site Research
N/A

4.0 Research Data Source/s

4.1 Primary Data: Subjects and Specimens
Primary data will be collected from subjects in this study. Subjects will consist of adolescents age 14-17y in the greater New Brunswick, NJ area.

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details
Following IRB approval, subjects will be recruited from the greater New Brunswick, New Jersey area. Advertisements will be posted in the local community (e.g., at community centers, YMCAs, boys and girls clubs, libraries, high schools etc.) and on Rutgers University and Robert Wood Johnson Medical School campuses. We will seek approval from all locations before posting advertisements.

B. Source of Subjects
Participants will be recruited from the greater New Brunswick, New Jersey area.

C. Method to Identify Potential Subjects

Individuals will be screened for eligibility via a phone screen to minimize participant travel-burden to the study center. Upon arriving to the study center for the orientation visit, additional checks for eligibility (BMI, typical sleep and availability to complete the study) will be completed initially to avoid wasting the time of ineligible participants. Those that meet the inclusion/exclusion criteria and are considered eligible for the study will be provided with an overview of the study, the informed consent process, and asked if they would like to enroll. Enrollment will occur at the study orientation.

In accordance with the protocol modification Mod2018002469, subjects who were previously screened and determined ineligible based on weight status alone will be rescreened. Subjects who previously completed the phone screening questionnaire were asked if they would like to be contacted for future research studies. Only those who gave permission to be contacted will be contacted and rescreened.

D. Subject Screening

A brief online screening questionnaire will be used for subjects who express interest in the research study. The online screening form will include the following topics: contact information, subject age, availability to complete the study, sleep habits.

After the study staff receives contact information from an interested individual, the individual will be contacted for a phone screen. The subject's parent will be asked to provide oral consent over the phone during the primary screening process to obtain confidential information related to eligibility and orientation scheduling. The parent will be read a statement of confidentiality (See Screening Script). A list of the items that will be covered in the screening interview will be read to the parent to ensure that the parent is aware of the screening process and the questions that are going to be asked of them. Study staff will ask the parent if they have questions or concerns prior to asking for oral permission and proceeding with screening-related questions. The study staff will ask the parent for permission to document identifiable information related to the subject's eligibility in the study. Verbal consent to the screening protocol will be documented on the Screening Script. The person obtaining oral consent will also sign and date this form. Initial eligibility will be determined using this screening tool and minimizes subject burden to the study location for the secondary screening and orientation. The phone screening script includes self-reported information including age, approximate weight and height of the child, availability to complete the study and current sleeping patterns.

Subjects who were previously screened for the research study will be screened again with an abbreviated screening form to capture transient data that may have changed from the initial screen (See Abbreviated Phone Screen). This abbreviated phone screen will include the following information: age, height and weight status, sleep habits, current enrollment in another research study and caffeine use. The research staff will provide the subject with both the study description and the confidentiality statement. Permission to document all variables will be obtained from the subject's parent.

Eligible individuals will be invited to the sleep center for an orientation. A secondary screening process will be needed to determine further eligibility (See Orientation Eligibility Form). We anticipate that a secondary screening process prior to the full written informed consent/assent process will minimize subject burden. Oral consent and assent from both the parent and child will be documented on a secondary screening document by the research coordinator/research assistant(s) to carry out procedures for additional checks for eligibility (measured BMI, typical sleep and availability to complete the study, complete the SDI-S questionnaire). These procedures are outlined in the Orientation Eligibility Form, which will be used to inform the parent and child about the orientation screening procedures. Study staff will ensure that the parent and child do not have any follow up questions or concerns. After oral consent and assent is obtained from both the parent and child, the research staff member who delivered this information will sign and date the form.

Following the additional screening procedures highlighted above, eligibility will be determined by the study staff based on inclusion/exclusion criteria. Eligible subjects will be asked to complete the written Parental Informed Consent Document and Assent of Participation in Research Activities Document before further research procedures can take place (See Consent section for further details on consent/assent process).

- **Inclusion Criteria**
  1. Parent-reported child age of 14-17 years
  2. Typical sleep duration of approximately 7hr/night on school nights
  3. BMI for age and gender in the >5th percentile but not greater than 100% overweight.
  4. Parent must be the primary caretaker and at home during bed/wake times
  5. Reported willingness and ability to complete all study-related tasks, including wearing the wrist actigraph and hip accelerometer daily.

- **Exclusion Criteria**
  1. Diagnosable sleep disorder (including Sleep Disordered Breathing) based on parent report and participant's score on Sleep Disorders Inventory for Students-Adolescents (SDIS-A).
  2. Medication use or parent-reported diagnosis of a serious medical condition (including psychiatric conditions) that may impact sleep.
  3. Excessive intake of caffeine (>300mg/day), drug (including nicotine) or alcohol use, or a history of substance abuse.
  4. Actively trying to lose weight.
  5. Transmeridian (east-west/west-east) travel during past month or planned travel during study time frame.
  6. Inability to understand or complete protocol to ensure that consent/assent and reliable and valid measures are obtained.
  7. Sibling of enrolled subjects, to minimize risk of bias in study findings.

E. Recruitment Materials
Printed flyers will be distributed across the Rutgers University campus. Additionally, we may reach out to local high schools, boys and girls clubs, libraries and YMCAs to advertise with printed flyers. Final versions of the print advertisements will be included for review, and we will seek posting approval from all locations prior to posting.

F. **Lead Site Recruitment Methods**
N/A

4.3 Subject Randomization
Condition assignments will be created by the PI and placed in sealed envelopes. Envelopes will be opened during the orientation visit by the study coordinator (there will be n=15 control and n=15 increase to 10h time-in-bed).

4.4 Secondary Subjects
N/A

4.5 Number of Subjects

A. Total Number of Subjects
We anticipate 30 total subjects to enroll in this pilot study.

B. Total Number of Subjects If Multicenter Study
N/A

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4.6 Consent Procedures

A. Consent

- **Documenting Consent**

The subject's parent will be asked to provide oral consent over the phone during the primary screening process to obtain confidential information related to eligibility and orientation scheduling. The parent will be read a statement of confidentiality (See Screening Script). A list of the items that will be covered in the screening interview will be read to the parent to ensure that the parent is aware of the screening process and the questions that are going to be asked of them. Study staff will ask the parent if they have questions or concerns prior to asking for oral permission and proceeding with screening-related questions. The study staff will ask the parent for permission to document identifiable information related to the subject's eligibility in the study. Verbal consent to the screening protocol will be documented on the Screening Script. The person obtaining oral consent will also sign and date this form. Initial eligibility will be determined using this screening tool and minimizes subject burden to the study location for the secondary screening and orientation. The phone screening script includes self-reported information including age, approximate weight and height of the child, availability to complete the study and current sleeping patterns.

Eligible individuals will be invited to the sleep center for an orientation. A secondary screening process will be needed to determine further eligibility (See Orientation Eligibility Form). We anticipate that a secondary screening process prior to the full written informed consent/assent process will minimize subject burden. Oral consent and assent from both the parent and child will be documented on a secondary screening document by the research coordinator/research assistant(s) to carry out procedures for additional checks for eligibility (measured BMI, typical sleep and availability to complete the study, complete the SDI-S questionnaire). These procedures are outlined in the Orientation Eligibility Form, which will be used to inform the parent and child about the orientation screening procedures. Study staff will ensure that the parent and child do not have any follow up questions or concerns. After oral consent and assent is obtained from both the parent and child, the research staff member who delivered this information will sign and date the form.

Following the additional screening procedures highlighted above, eligibility will be determined by the study staff based on inclusion/exclusion criteria. Eligible subjects will be asked to complete the written Parental Informed Consent Document and Assent of Participation in Research Activities Document before further research procedures can take place (See Consent section for further details on consent/assent process)
A parental informed consent document will be used to obtain consent from the parent of the participant. Additionally, because we are recruiting children, every child will be asked to provide assent and will sign the assent document to declare assent to research study procedures.

Document List:

a. Parental Informed Consent Document
b. Assent for Participation in Research Activities Document

On the consent form, we ask parents to indicate if they are willing to be contacted in future research studies. If a parent initials 'Yes, I agree to be contacted about future research studies,' we will provide them with a Contact Form which will include the name of parent, the name of the participant, the date as well as the preferred contact method. Parents and participants will be informed that in the event there is another research study they can participate in, the study staff will contact the family using the information provided on the Contact Form. The

Contact Form is the only document used to revisit families that documented interest in participation in additional research studies at Rutgers Sleep Lab.

- **Waiver of Documentation Of Consent**

N/A

- **Waiver or Alteration of Consent Process**

N/A

6.

7. Consent Process

- **Location of Consent Process**
  The consent process will take place in Loree Classroom Building in a closed-door office space.

- **Roles for Individuals Involved in Consent**
  The study coordinator will be responsible for obtaining written consent/assent at the initial orientation visit from both the parent and the child.

- **Coercion or Undue Influence**
  The consent process is anticipated to take approximately 10-20 minutes, or as long as the participant needs to make an informed decision about participation in the study. All individuals involved in the informed consent/assent process will be educated that their participation in the research study is completely voluntary. Participants will be reminded that they have the ability to withdraw at any time and that their decision to participant will not have any impact on their availability of care. All study-related information will be clearly communicated and in writing in an organized fashion with understandable language. Exculpatory language will not be used in written consent or discussions about research.

4.7 Special Consent/Populations

A. Minors-Subjects Who Are Not yet Adults

- **Criteria for Consent of Minors**
  Parents will be asked to report the age of their child prior to study enrollment. This research study will focus on adolescents (14-17 y), and therefore, we expect a parent to be available and present at all study meetings.

a. Wards of the State
N/A

b. Research in NJ Involving Minors
This research involving children will pose no more than minimal risk to the participants. Permission of one parent is sufficient event if the other parent is alive, known, competent, reasonably available, and share legal responsibility for the care and custody of the child. Assent to research procedures will be obtained from all children. The investigators will obtain assent on the Assent for Participation in Research Activities Form. The child will print, sign and date the assent form. Parental consent will be obtained using the Parental Informed Consent Form. The name of the child will be printed on the form, and the parent will print, sign and date the form. The person obtaining consent will sign and date both the parental consent and assent forms before enrollment can occur.

c. Research Outside of NJ Involving Minors
N/A

- **Parental/Guardian Permission**
  Participants in our study will be between the ages of 14-17 years. Therefore, parental permission to participate in the research study will be required.

- **Assent Process**
  During the orientation, trained study staff will go through the consent document with the parent. The parent will have the opportunity to ask questions about the study. Next, the stuff staff member will review the assent form with the child to ensure that the child has a clear understanding of the study procedures. Research staff members will ask the child if they have any questions or concerns related to the study protocol. The study staff will remain engaged with both the child and the parent during the entire duration of the consent/assent process. Following review of the consent and assent documents, the parent and child will have the opportunity to discuss the study. After the decision is made, and the study staff ensures that all questions and concerns have been addressed, the parent will be asked to sign the consent document and the child will be asked to sign the assent document. We will obtain assent for all children who have parent consent to research participation. Individuals will be asked about any questions or concerns they may have prior to assent and also be made aware that their participation is completely voluntary.

  a. Documentation of Assent
  Trained study staff will review the assent form with the child while the parent is present. Assent will be considered documented after the child prints, signs and dates the Assent for Participation in Research Activities Form.

B. Non-English Speaking Subjects
N/A

C. Economic Burden and/or Compensation for Subjects

- **Expenses**

The only expense that participants are anticipated to accrue as a direct result of participation in this study is the cost of travel to the sleep center.

- **Compensation/Incentives**

At the end of the follow-up visit, when devices have been returned, participants will be compensated ($10/day = maximum $70 for their participation in the study according to protocol adherence (payments will be made in the form of a giftcard).

- **Compensation Documentation**

Participants who adhere to the protocol guidelines described at the orientation will receive a receipt of the payment and study staff will make copies of these receipts. Receipts will be stored in a locked filing cabinet in a locked office.

D. Risks and Benefits to Subjects

- **Description of Subject Risk**

The sleep study procedures pose minimal risk to participants. Participants will be asked to wear sleep monitoring and physical activity devices, and there is a rare risk (estimated at 1 out of 100 persons) that the devices may cause irritation to the skin or be slightly uncomfortable to wear.

Participants may experience travel inconvenience, as they are asked to travel to the study center for orientation and the follow-up visit. We will ask participants to complete sleep diaries and complete daily call-ins to report sleep patterns, which may serve as a small inconvenience to participant participation. Half of participants will be asked to increase their sleep to 10 h/night. A change in sleep patterns, bedtime routine or wake routine may be an emotionally charged or negative psychological experience for the subject and/or their families.

Participants will be asked to complete a sleep disorder questionnaire upon study enrollment to determine if they have a sleep disorder that would hinder their ability to participate any further in the research study. Therefore, there is a risk that the participant may endure psychological stress as a result of completion of this assessment.

There is a rare risk that confidentiality of the subjects and/or their families may be broken. However, the study staff will be trained to minimize these risks to ensure confidentiality is not broken before, during and after data collection.

- **Risks to Non-Subjects**

The subject's parent(s) will need to be engaged in the research study in order to ensure that the child is following the study protocol. Changes in behavior that may be attributed to study protocol procedures may be a psychological risk to non-subjects, as the study protocol may disrupt daily activities. Additionally, parents are expected and will be required to travel to the study center their child, and therefore, they may experience a travel inconvenience for their time.

- **Minimizing Risks**

In order to minimize risk, the research team will be composed of members who have sufficient expertise and experience to conduct the research. Actigraph and accelerometer data will be collected using standard procedures. The study staff will be trained in device placement to ensure that the participant is comfortable before leaving the sleep center. An unknown preexisting condition that is discovered at the research lab will prompt the study staff to explain to the participant that they need a clinical examination to determine their condition and that no medical diagnosis has been made. Additionally, study staff will have resources available to subjects in the event that they ask for further medical advising related to the condition. Data confidentiality will be protected by storing all data on a secure server recommended by Rutgers IT department on a password protected computer. All hard copies of participant data will be stored in a locked filing cabinet in a locked office space.

- **Certificate of Confidentiality (CoC)**

N/A (will not be obtained; not funded by NIH)

- **Potential Benefits to Subjects**

At the follow-up study visit, trained study staff will have the capacity to share individualized sleep reports with the study participants and their families. These sleep reports may be a valuable tool for participants to learn about their own sleep habits. Educational materials will also be distributed to the parents to help the adolescent improve sleep. Additionally, participants will be compensated according to study protocol adherence. Adherence will result in a maximum compensation of $70.

- **Provisions to Protect the Privacy Interests of Subjects**

The study coordinator will be responsible for coordinating all aspects of research that involve confidential information, including participant scheduling, orientation, participant call-ins and follow up visit to ensure subject

privacy is protected. Participants will be instructed to contact the study coordinator with any questions or concerns related to the study protocol, which will limit the number of investigators that may be aware of the participant's and his/her parent's identity.

- **Research Team Access to Subject Data**

The study coordinator and PI will have access to a password-protected folder on a shared drive which will contain the data collected from the study.

4.8 Secondary Data

N/A

A. Chart/Record Review Selection

N/A

B. Secondary Specimen Collection

N/A

- **Specimen Storable Procedures**

  N/A

- **Specimen Data**

  N/A

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 NJ Access to Medical Research Act

N/A

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. "Special" Classes Of Subjects

- Children in our study are defined as persons who have not attained the legal age for consent to procedures involved in the research. We plan to seek child assent, or a child's affirmative agreement to participate in research. Permission will be obtained via parental consent to allow their child's participation in the research. Parent is defined as a child's biological or adoptive parent. The study coordinator, trained in informed consent procedures, will obtain written informed consent for the parent of the child and written assent from the child before proceeding with study. We anticipate that the study procedures will present no more than minimal risk to the subjects who participate in the research.

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. As this is a pilot study, primarily descriptive statistics will be conducted on sleep and physical activity data. No formal analyses will be conducted on feasibility/acceptability questionnaire and subsequent interview responses. Mixed-model ANOVAs will compare changes in sleep and physical activity between both groups.

B. All data will be de-identified (a subject id number will be assigned to each participant and used to track each data file) and will be stored on a password-protected shared drive folder (the study coordinator and PI will be the only two with access to this folder).

C. All sleep and physical data will be separately independently by the study coordinator and PI to determine reliability in the application of scoring rules. Questionnaire data will be entered by two study staff members independently and then compared to ensure accuracy.

D. Sleep and physical activity data will be obtained from an output that the device software provide. This data will be checked against sleep diary and call-in data and adjusted as necessary by trained study staff. Questionnaire, sleep diary, sleep device and physical activity device data will be aggregated and entered in to a database in SPSS. This file will be stored on a password-protected shared drive folder. The study coordinator and PI will have access to this folder. The study coordinator is primarily responsible for receipt of the data and the PI will ensure its storage. The data will be stored for five years.

6.2 Data Security

Any data collected in this study, including demographic/health information and experimental testing, is solely for research purposes and will be kept in locked file cabinets with restricted access. Only the PI, co-investigators, and approved research staff will be able to access the stored data. Interview data, test results, and other information collected from participants will be identified using participant ID numbers to de-identify their personal name from the files. Only the PI (Dr. Andrea Spaeth) and the study coordinator will have access to the file that associates participant ID numbers to identifying information. Data collected in this study will be stored in locked filing cabinets and/or on password-protected computers. All signed consent forms will be maintained in a file separate from the individual participant's data. Five years following the completion of this study, the association between participant ID numbers and identifying information related to participants (e.g., names) will be destroyed.

6.3 Data and Safety Monitoring

The study protocol is not expected to cause more than minimal risk to participants.

6.4 Reporting Results

A. Sharing of Results with Subjects

Data collected using the sleep wrist actigraph will be downloaded off of the device and presented in a visual graph to the participants at the follow-up visit. Trained study staff will show the participants their average amount of sleep recorded for each night they wore the actigraph device to sleep.

B. Individual Results

Participants will be asked to complete a sleep disorders questionnaire. In the event a participant achieves a score that excludes them from the study, we will provide the participant with a referral to the Robert Wood Johnson Sleep Clinic.

C. Aggregate Results

N/A (Aggregate results will only be shared internally to inform the future study.)

D. Professional Reporting

If data is reported to other researchers and the scientific community for input in planning the future study, all subject identifiable information will be removed from the data set.

6.5 Data Sharing

The investigators will be responsible for protecting the rights of subjects and the confidentiality of the data during data sharing. Prior to sharing, data will be redacted to strip all identifiers to minimize the right of unauthorized disclosure of personal identifiers. Datasets will be stripped of items that could identify individual participants, including name, address, telephone numbers, etc.

Additionally, all subjects will be informed about data sharing in during the informed consent process to ensure that subjects are informed about the data sharing process.

7.0 Data and/or Specimen Banking

A. Storage Methods
N/A

B. Storage Data
N/A

C. Releasing Data/Specimens
N/A

8.0 Other Approvals/Authorizations

N/A

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