**HCL and Sleep Study ADA Abstract Data Analysis Plan**

ADA abstract submission **due January 10th, 2022**

Late breaking Feb 1st, 2022 through March 7th, 2022

**Data available in RedCap:**

**PARENT**

Baseline

* Parent Demographics
* Parent PSQI
* Parent PROMIS Proxy
* Parent PAID-PR
* Parent PedsQL
* Parent HFS
* Parent Diabetes Technology Questionnaire
* Parent INSPIRE Questionnaire
* Parent Sleep Diary
* Parent Actigraphy Watch

Week 1

* Parent Sleep Diary
* Parent Actigraphy Watch

3 Month

* (Same parent surveys)
* Parent Sleep Diary
* Parent Actigraphy Watch

6 Month

* (same parent surveys)
* Parent Sleep Diary
* Parent Actigraphy Watch

**CHILD**

Enrollment/Baseline (BL D2, etc are sleep diary days 2-7)

* Child Demographics
* Child PROMIS (ages 8-17)
* Child PAID-peds
* Child PedsQL
* Child HFS
* Child Diabetes Technology Questionnaire
* Child INSPIRE Questionnaire
* Child Sleep Diary
* Child Actigraphy Watch
* Child Glycemic data

Week 1 (HCL W1 D2, etc are Sleep Diary days 2-7)

* Child Sleep Diary
* Child Actigraphy Watch
* Glycemic Data

3 Month (D2-7 are sleep diary days)

* (same child surveys)
* Child Sleep Diary
* Child Actigraphy Watch
* Glycemic Data

6 Month (D2-7 are sleep diary days)

* (same child surveys)
* Child Sleep Diary
* Child Actigraphy Watch
* Glycemic Data

**Demographics Descriptive Data**

Parents:

* Age (Date of Birth in RedCap)
* Gender
* Race/Ethnicity
* Number of glucose checks per day
* Number of blood sugar checks at night (per week)

Child:

* Age (Calculate age in RedCap)
* Gender
* T1D duration (Date of T1D diagnosis in RedCap)
* Previous method of insulin (from Parent Demographics questionnaire)
* Previous CGM use (from Parent Demographics)
* Previous PLGS or HCL use (from Parent Demographics)

**Actiwatch Data Includes: (min and max also in Redcap, but won’t be used)**

Avg Bed Time

Avg Get Up Time

Avg Time in Bed

Avg Total Sleep Time

Avg Onset Latency

Avg Sleep Efficiency

Avg WASO

Avg number of awakenings

**Sleep Diary Data Includes:**

Time went to bed (date of bedtime)

Time woke up (date of wake time)

Nighttime awakenings

How well did you sleep?

**Scoring and RedCap Coding:**

Sleep Surveys

**PSQI** – See scoring instructions. All scores are on a scale of 0 to 3. RedCap currently scores all multiple choice questions 1 to 4.

**PROMIS** – See Instruction manual and scoring word document (can also upload data to the website, though requires a specific format <https://www.assessmentcenter.net/ac_scoringservice>)

**Children’s Sleep Habits Questionnaire** – Scored on a scale of 1 to 5. Mean of 18 items: 1, 2, 3, -4, -5, -7, -8, 10, -11, -12, -14, -15, -16, -17, -18, -20, -21, -22. RedCap scoring is 1 to 5.

Psychosocial Surveys

**PAID Peds** – Per Clinical Obs Scoring. 20 questions total. RedCap currently scores it 1 to 5.

**PAID PR (Parent Revised)** – Per Clinical Obs scoring plan. 18 questions total. RedCap currently scores it 1 to 4.

**PedsQL** – Scored on a scale of 0 to 4. Redcap currently has it scored on a scale of 0 to 4. This is more complicated, see scoring instructions.

**HFS** – See previous scoring including score for Total, and subscales for Maintain High BG Behavior, Helpless/Worry about low BG, and Worry about negative social consequences. RedCap currently has it scored on a scale of 1 to 5. Of note, CHILD HFS is missing question 18 (so the RedCap question 18 is actually question 19 from the actual survey, etc)

Device Surveys

**Diabetes Technology Survey** – Per Clin Obs scoring. On a scale of 1-5. RedCap currently has it scored 1-5.

**INSPIRE survey** – Per Clin Obs scoring. RedCap currently has it scored 1-6 (6 being N/A).

**Abstract Analysis Plan**

**Participants**

Please exclude subjects 101/201, 102/202, 103/203, 110/210, 119/219, 121/221, 131/231, 141/241 (Withdrew after enrollment or were ineligible)

**Demographic Analysis**

Parents:

* Age (Date of Birth in RedCap)
* Gender
* Race/Ethnicity
* Number of glucose checks per day
* Number of blood sugar checks at night (per week)

Child:

* Age (Calculate age in RedCap)
* Gender
* T1D duration (Date of T1D diagnosis in RedCap)
* Previous method of insulin (from Parent Demographics questionnaire)
* Previous CGM use (from Parent Demographics)
* Previous PLGS or HCL use (from Parent Demographics)

**Abstract 1 (Aim 1):**

Authors?: Erin Cobry, Angela Karami, Emily Jost, Lisa Meltzer, Laura Pyle (and/or Tim), Paul Wadwa

* Changes in **Actigraphy Data (Total sleep time, sleep efficiency, and WASO) (Parents and Child)** and **Sleep survey data** **[PSQI (Parents) and PROMIS (child self-report) and PROMIS parent proxy (Child)]** over time (Comparison of Baseline to 3 months and 6 months)
  + Question being asked: Does use of CIQ improve sleep outcomes, both subjective and objective, for parents and children with T1D?
* Evaluate the number of participants achieving sufficient **sleep duration on actigraphy** (per recommendations): **Parents** should get 7+ hours. **Children 1-2** **years** should get 11-14 hours, **3-5 years** should get 10-13 hours, **6-12 years** should get 9-12 hours, **13-17 years** should get 8-10 hours.
  + Question being asked: How many parents and children are meeting the sleep recommendations at baseline, 1 week, and 3 and 6 months?
  + Was there a significant change in the number of patients achieving recommended duration of sleep (parents separate from all children combined)

**Abstract 2:**

Authors?: Angela Karami, Laura Pyle (and/or Tim), Emily Jost, Paul Wadwa, Lisa Meltzer, Erin Cobry

* **Sleep diary** data for **both Parents and Child**: **Number of nighttime awakenings**, **duration of awakenings,** and **causes of nighttime awakenings** (e.g. looking at specific diabetes related awakenings vs non-diabetes related awakenings). [This may require manual review of the comments and categorizing the causes of awakenings]
  + Comparison in the frequency of nighttime awakenings by sleep diary from baseline to 3 months and 6 months.
  + Question being asked: Are there significant differences in the number of reported nighttime awakenings after starting Control-IQ and how many of those are diabetes specific?