



SLEEP MATTERS

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UPCOMING NARCOLEPSY FOCUSED SLEEP² MEETING

The 2nd **Strategically Engage, Leverage, and Empower PCOR (Patient Centered Outcomes Research) in Sleep (SLEEP²)** Conference is being held in Boston, MA on June 3rd, which will have a narcolepsy focus. The exciting line-up of speakers includes Emmanuel Mignot, Narong Simakajornboon, Julie Flygare, and Rebecca Fuoco. There will also be a networking blitz to showcase new research. There are no registration costs for this meeting but travel and accommodation is on your own.

Registration Link:

http://qeasttrial.co1.qualtrics.com/SE/?SID=SV_4Jb5zD8gsvhi4MR

NEWS of WEARABLES & GENETICS WORKGROUP MEETINGS

Highlights from the Wearables & Genetics Workgroups, two of three workgroups that met to discuss how to facilitate interinstitutional collaborations during the October 2016 SRN meeting are summarized below.

WEARABLES WORKGROUP: Co-Chairs: Reena Mehra & Janet Mullington

Identified Need: At the Sleep Research Network meeting break-out discussion on wearable devices, there was consensus that the field needs validated device(s), (i.e. tested against PSG that could be recommended for research), which could be used by clinicians to monitor patients and also inexpensive enough to enable easy access by health and fitness conscious consumers. However, while there is need for a device that approximates current gold standards, there is also a need to develop methods of analysis that could be used with currently available signals to develop new ways to characterize sleep. Another identified technology gap is the need to develop novel technologies to characterize and track sleep.

Goals:

1. Validity:

The field needs a measure that can track closely with the gold standard of polysomnographically-defined sleep

2. Accessibility

Networking Opportunities in Sleep Medicine

SRN PCORI SLEEP² Engagement Meeting

*Saturday June 3rd, 2017,
Sheraton Boston Hotel @
39 Dalton St, Boston, MA
02199.*

Registration begins at 7:45am and the conference starts at 8:45am.

**Contact Cody Havens
(chavens@email.arizona.edu)
if you want email updates
about this activity.**

Contribute to this Newsletter

We are inviting submissions to this newsletter that could feature collaborative research that you may be doing in sleep and circadian sciences. Please contact the editor for further details.

The device(s) developed to track sleep need to be inexpensive and available to consumers, fitness experts and trainers, and clinical providers. Definitions of terms need to be very clearly defined and as jargon-free as possible.

3. Standardization

Within a class of devices, standardization of terms (vocabulary, harmonized terminology) is important for validity, particularly in the research domain, so that results of different studies and application of technologies in different settings can be better appreciated.

4. Utility

A device proves its utility by providing information that is easily obtained, is accurate and reliable, and with outcome reference that is meaningful to the user. For example, the meaningful benefit and impact to the care of the patient was discussed with ability to interface and integrate with the electronic medical record. Examination of the benefits in the realm of health literacy and biobehavioral health was another priority area which was discussed.

Potential Barriers: The group discussed opportunities to partner with industry and develop technological products and algorithms that meet needs of clinicians, trainers and individual consumers, alike. There are several barriers to the advancement of technology development and transfer, including the ones mentioned below.

- Company's proprietary restrictions
- FDA and regulatory challenges
- Differences in Industry, University and Medical Center HIPPA, compliance regulations, ownership of data and COI
- Cost related - Time to profit return is important
- The sleep field needs to see demonstrated validation with sleep-wake, even if raw data is not provided or accessible, therefore lack of transparency of existing algorithms remains a barrier.
- Chosen platform may have implications for working with patient data
- Access issues – where does data reside and who can access how?
- Profit and Intellectual Property – Industry-University-Medical and Research Institutions working together can be logistically and legally challenging
- Business venture works on a different time scale than research, and this needs to be considered in planning and development of milestones and deliverables.

Partners: The group discussed potential stakeholders to bring together to partner in getting wearable technologies to the next level. A list of groups that should be at the table include:

- Patients
- Clinicians
- Public
- Institutions
- Industry (Established and venture capital groups)
- Patient advocacy groups
- Health Data Exploration Society
- Health insurance organizations
- IRBs (One IRB, SMART IRB <https://smartirb.org/>)
- Wellness programs
- Professional organizations/societies
- Safety organizations/stakeholders

Next Steps: The group discussed the importance of identifying partners who can help define goals and deliverables and a means to develop infrastructure. Convening a working group of partners (from above) and creating a roadmap to bridge the hurdles of technology research, development and transfer are priorities. It was recognized that scientists need training on how to interact with industry as stakeholders. Investigators need their institutions to help navigate compliance at IRB, fiscal, and intellectual property levels. Institutions can help with innovations to build translation from basic and engineering research domains to translate to clinical application and public utility. Potential funding sources need to be identified and include SBIR mechanisms and Industry.

Genetics Workgroup: The workgroup, which included Mariska Brown, Brian Cade, Clete Kushida, Maria Pompeiano, Susan Redline, and Patrick Strollo identified and prioritized three goals for sleep-related genetics that they believe are most pertinent and important to the field.

Goals:

1. Data sharing and cross-collaboration by large groups for genome-wide association studies (GWAS):
 - a. Routinely-collected clinical data (identifying appropriate sleep data in electronic health records); and
 - b. Research data collaborations (shaped by governance-defined structure)
 - i. Model: United Kingdom collaborations for actigraphy and oximetry data
2. National registry for phenotypes identifying different genetic and environmental risk factors – need to establish homogeneous and informative data structures
 - i. Model: Inspire hypoglossal stimulation studies
3. Biobanks (need central mechanisms to manage genotyping) and biorepositories (e.g., sleep questionnaires, polysomnograms)

Potential Barriers: The workgroup identified and prioritized concerns/challenges that may prevent the achievement of these goals:

- Data sharing (models are available)
- Governance (models are available)
- Assessing simple/scalable sleep phenotypes (that need standardization and replicability) in research studies and the capturing of these data in clinical databases
- Funding, especially for individuals to prepare datasets at institutions for data sharing
- Identifying appropriate cells to collect (e.g., blood, biopsies of fat, tongue, brain?), how to collect them, who is collecting them, and other practical and logistical issues (e.g., there are not many technologists with phlebotomy certification)
- Using commercial wearable devices (vs. actigraphy) in phenotyping (overlap with SRN Wearable Working Group)
- Attracting basic science researchers to network meetings (vs. clinical researchers interested in multicenter trials)

Next Steps: The workgroup identified and prioritized the next steps/deliverables (i.e., milestones) for advancing this area:

1. Infrastructure/shared resources
 - a. Start off with top 5 phenotypes (e.g., oximetry, insomnia severity index, actigraphy, PROMIS sleep impairment (vs. Epworth sleepiness scale), melatonin assay, Psychomotor Vigilance Task [PVT])

- b. Collect data in a systematic, standardized manner
2. Communication/outreach
 - a. Establish a working group (consensus across SRN, AASM, SRS, SDRAB)
 - b. Sleep center sharing of databases and need to identify experts in specific basic/clinical research areas (perhaps through a SRN survey)
 - i. Model: sleepgenetics.org
3. Funding
 - a. NHLBI funding to collect biospecimens, genotyping (*see Partners Section*)

Partners: The workgroup identified partners who could assist the SRN in achieving its goals:

1. Potential Partners
 - a. NHLBI – for every sleep-related study that meets criteria for sharing (e.g., adequate sample size), provide an administrative supplement for sharing data that will be placed in a central biorepository (more cost-effective than funding a network)
 - b. Industry (e.g., Inspire)
2. Timeline for each deliverable: Establish a workgroup (ASAP)

UPCOMING EVENTS

SLEEP² meeting, Saturday June 3rd, 2017, Boston, MA. The thematic focus will be on *Narcolepsy* and co-led by Project Sleep.

Annual SRN Meeting, Monday September 25th, Bethesda, MD.

SLEEP² meeting, Tuesday September 26th, 2017, Bethesda, MD. The thematic focus will be on *insomnia*.

HealthMeasures User Conference, September 27–28, 2017, Chicago, IL, <http://us14.campaign-archive1.com/?u=5189d55fa5eb9f841e18c3125&id=9e563992ec&e=dc37113c68>, abstract submission deadline extended until April 7, 2017.

The SRN is a membership organization of sleep and circadian researchers that was created in 2008 by sleep and circadian researchers from institutions that had received the National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA).



SRN Mission Statement

The mission of the SRN is to promote sustainable, multi-institutional collaborations that address significant public health questions in sleep medicine and circadian biology, while also attracting and supporting training for the next generation of sleep medicine investigators. We address our goals through an annual meeting, network communications and project development, and collaborative grant applications.

SRN Website

<http://www.sleepresearchnetwork.org/>

SRN Newsletter

Editor: Ellis Boudreau, MD, PhD boudreau@ohsu.edu.