November 24, 2010

To: Fred W. Turek, Ph.D.
Charles E. & Emma H. Morrison Professor of Biology
Director, Center for Sleep and Circadian Biology
Northwestern University

RE: **External Advisory Board Report for Northwestern University (NU)-American Waterways Operators (AWO) Towboat Project Entitled, "Integrating the Crew Endurance Management System (CEMS) with anchor sleep/nap sleep strategies to reduce fatigue and risk on towing/barge vessels"**

External Advisory Board Members:

Dr. Gregory Belenky
Sleep and Performance Research Center
WSU Spokane
412 E. Spokane Falls Blvd.
P.O. Box 1495
Spokane, WA 99210-1495
phone: (509) 358-7738
fax: (509) 358-7810
email: belenky@wsu.edu

Dr. Andrew Monjan
Monjan & Associates
7138 Rivers Edge Road
Columbia, MD 21044-4235
phone: (410) 531-3832
email: amonjan@mac.com

Dr. Kenneth P. Wright, Jr. (Chair)
Director, Sleep and Chronobiology Laboratory
Department of Integrative Physiology
University of Colorado
Boulder, CO 80309-0354
phone: (303) 735-6409
fax: (303) 492-4009
email:kenneth.wright@colorado.edu

This letter serves as the report of the External Advisory Board (EAB) for the Northwestern University (NU)-American Waterways Operators (AWO) Towboat Project Entitled, "Integrating the Crew Endurance Management System (CEMS) with anchor sleep/nap sleep strategies to reduce fatigue and risk on towing/barge vessels"

The EAB would like to congratulate Professor Turek, his investigative team and the participating towing/barge companies for gathering important preliminary data on towing/barge operations under difficult, real-time operational conditions. The towing/barge vessel research project to reduce fatigue and sleepiness is of high importance for the CEMS, for public safety, and for reducing economic risks associated with reduced productivity and increased accidents. Work schedule induced fatigue and accident risk associated with inadequate/disturbed sleep are well recognized in other operational environments. The initial efforts of the towing/barge vessel project are very valuable and clearly demonstrate limited sleep during towing/barge operations and thus the need for implementation of a sleep fatigue management program as part of the CEMS for towing/barge vessels in America's waterways.

The educational component of the sleep CEMS to improve the sleep environment on vessels, the sleep behaviors of crewmembers, and to recognize symptoms of untreated sleep disorders are viewed as very positive. The anchor sleep/nap sleep strategy to reduce fatigue on towing/barge vessels is responsive to the sleep fatigue management needs in this operational environment and represents implementation of evidence based sleep and circadian science. Additional research is warranted to determine whether the anchor sleep/nap sleep strategy is effective at increasing total sleep per 24h for the Captain/Front watch. Additional research is also needed to evaluate the effectiveness of anchor sleep/nap sleep strategy during the circadian misalignment associated with the Pilot/Back watch. The use of actigraphy and daily logs to assess sleep is appropriate and a strength in the current operational setting.

The EAB provides the following recommendations for ongoing and future towing/barge vessel research efforts, recognizing that implementation of some recommendations may require additional funding support.

1) The EAB recommends additional research to further document limited sleep during towing/barge vessel operations and to discover factors that lead to disturbed sleep. Future projects should explore possible reasons why those on the Captain/Front Watch do not appear to have better sleep than those on the Pilot/Back Watch. This should involve sample sizes yielding sufficient power to detect the apriori expected differences. From a circadian perspective, the nighttime sleep opportunity of the Capitan's watch should be the optimal biological time to obtain a minimum of 5-5.5 h out of the 6h sleep opportunity. The short total sleep time for all crewmembers across 24h suggests that multiple factors may disrupt sleep during vessel operations. Therefore, factors that disturb sleep in addition to reduced sleep opportunities should be explored; e.g., 1) operational demands; 2) environmental factors such a noise, temperature, odors, vessel movements, and light; 3) untreated sleep disorders; 4) behaviors that disturbed sleep (e.g., using caffeine, performing other tasks during the anchor

sleep opportunity); and 5) other factors specific to the towing/barge vessel environments.

Specific recommendations follow:

a) Consider including assessment of possible sleep disruptors in sleep logs.

i) How many times did you awaken the last sleep episode?
ii) How long did you sleep?
iii) Was your sleep disturbed and why? Include check boxes for common factors based on prior interviews to make reporting of factors easy (e.g., noise, too hot, too cold, odors, work duties, awaken to void, other crewmembers, physical discomfort, other disturbances).
(a) In future studies, environmental factors such as noise, temperature, work load, changes in engine noise and boat movement that might awakening crewmembers needs to be assessed.
(b) Such information can be used to improve the sleep environment and sleep behaviors of crewmembers.
iv) Did you use any caffeine during the last work shift; if so, what kind and how many cups/ounces?
v) Indicate how long before bed was your last caffeine intake?
vi) Did you use any medications during the last work shift; if so, what kind?

b) Consider using visual analog scales or Lickert scales with a larger range to improve sensitivity of outcome measures (e.g., how did you sleep last night?).

c) Consider measurement of noise, light, and temperature levels in vessel sleep quarters using sound, light and temperature recording devices.

d) Consider using actigraphy for assessment of sleep timing, total sleep time, wakefulness after sleep onset and sleep efficiency across the entire 24h actigraphy record in addition to using interval between bedtime and waketime as derived from the sleep diaries. The 24h record analysis will be sensitive to undocumented naps (i.e., let the sleep scoring algorithm score the entire record). Reconsider the use of actigraphy for the assessment of sleep onset latency as current actigraphy guidelines indicate that actigraphy is not an accurate marker of sleep latency. Use of subjective sleep latency from the daily sleep diary would be an appropriate measurement of sleep latency.

2) Evaluation of the anchor sleep/nap sleep strategy is viewed as a high priority. The EAB recommends development of a research study to test the anchor sleep/nap sleep intervention on the 6:6:6:6 tour schedule. The EAB recognizes that the Phase II trial was not methodologically designed to test the effectiveness of the

anchor sleep/nap sleep intervention, but rather to determine if crewmembers could increase sleep time.

a) Consider designing a cross-over research study or one with a control group that is not exposed to the anchor sleep/nap sleep intervention. The intervention could be tested in a controlled laboratory study or in an operational evaluation.

b) Consider assessment of sleep of crewmembers across a month or two during off duty and during towing/barge operations. Such sleep-wake history could be input to a mathematical model that predicts performance, e.g., a model like SAFTE/FAST.

c) If outcome measures such as the PVT are to be used in future research, the EAB recommends that standardized methods be used to ensure that crewmembers take the test under more controlled conditions while on the towing/barge vessels. Furthermore, as the PVT is sensitive to cumulative sleep loss, consideration of the use of a control group without the anchor sleep/nap sleep intervention may need to be considered if the PVT is to be used as an outcome. The sensitivity of the PVT to the intervention may also be improved by use of a standard 10 min version versus the 5 min PVT version, although time constraints may limit such assessment; and assessment of lapses and median or 1/mean reaction time, not the mean reaction time.

d) Consider implementation of a sensitive sleepiness measurement tool, such as the Karolinska Sleepiness Scale (KSS), at a measure of on the job sleepiness.

3) The investigative team is well suited to develop and implement the sleep based CEMS program. The EAB recommends that biostatistician expertise be added to the investigative team to improve evaluation of the program. The EAB recognizes that the number of subjects that can be studied under real-world operational settings is limited. Thus, evaluation of findings may need to include consideration of trends in the data that do not reach statistical significance. In the current phase of the research, much in the way of questionnaire data will be collected, but the small sample sizes will preclude very much in the way of multivariate analyses.

   Specific recommendations include:

   a) Consult with a biostatistician experienced with small sample size analytic methods.

   b) Consider use of newer statistical techniques that can handle missing data and individual differences in response to conditions.

c) As crewmember tour work hours may differ across boats, the inclusion of number of consecutive days of work and prior rest could be considered.

d) As an exploratory analysis, consider adjusting confounding factors such as age, BMI/obesity, ESS, mood disorders, caffeine and medication intakes, health status, environmental parameters, workload condition, etc.

e) Consider adjusting for suspected untreated sleep disorders. An alternative option is to consider analyzing outcomes with and without subjects with untreated sleep disorders.

f) Consider using the preliminary findings from the phase II trial in power calculations when designing future trials. Recommend studies be powered to detect differences in actigraphically measured sleep.

4) Untreated sleep disorders represent a significant concern for sleepiness/fatigue related accidents in AWO. Untreated sleep disorders also contribute to reduced productivity, increased sick days, and poor health outcomes. Preliminary findings from Phase II suggest that the high BMI in some crewmembers puts them at risk for sleep apnea. Recognition and referral of individuals with suspected untreated sleep disorders will significantly contribute to the sleep CEMS strategy. Individuals with untreated sleep disorders likely require intervention in addition to the anchor sleep strategy to show improvements in sleep duration. In addition to educating crewmembers, the EAB encourages the investigative team to educate towing/barge companies about the economic and safety value of screening crewmembers for sleep disorder symptoms at medical checkups.

5) The EAB recommends that the investigative team evaluate the outcomes of the sleep education program. The use of established sleep knowledge questionnaires from the National Sleep Foundation or other sleep organizations can be considered.

6) Modified/additional interventions to consider:

a) Given the equal length of anchor and nap sleep opportunities in the 6:6:6:6 tour schedule, the classification of nap versus anchor sleep could be empirically defined. If crewmembers are instructed to obtain the most sleep possible during each 6 h opportunity, sleep may be distributed similarly across each 6 h block to obtain adequate 24h total sleep duration especially when crewmembers are sleepy. Related, given that sleep durations are limited even on the Captain's watch, the anchor sleep - nap sleep distinction may not be necessary.

b) Consider the use of exogenous melatonin (5mg) or if an FDA approved drug is desirable, Ramelteon (8mg) to promote sleep when crewmembers attempt sleep outside of the 2400-0600 h Captain's watch.

c) Consider shifting the square watch for example by three hours, anchoring it on 0300 h to even out the favorableness of sleep opportunities for the two watches. A comparison could be made between the shifted and non-shifted 6:6:6:6 square watch schedule. Figures in the Appendix illustrate the time spent asleep over the circadian cycle while on a 90 minute day (Buysse DJ; Monk TH; Carrier J et al. Circadian patterns of sleep, sleepiness, and performance in older and younger adults. SLEEP 2005; 28(11):1365-1376). Blue is Captain's Watch, red is Pilot's Watch).

Appendix

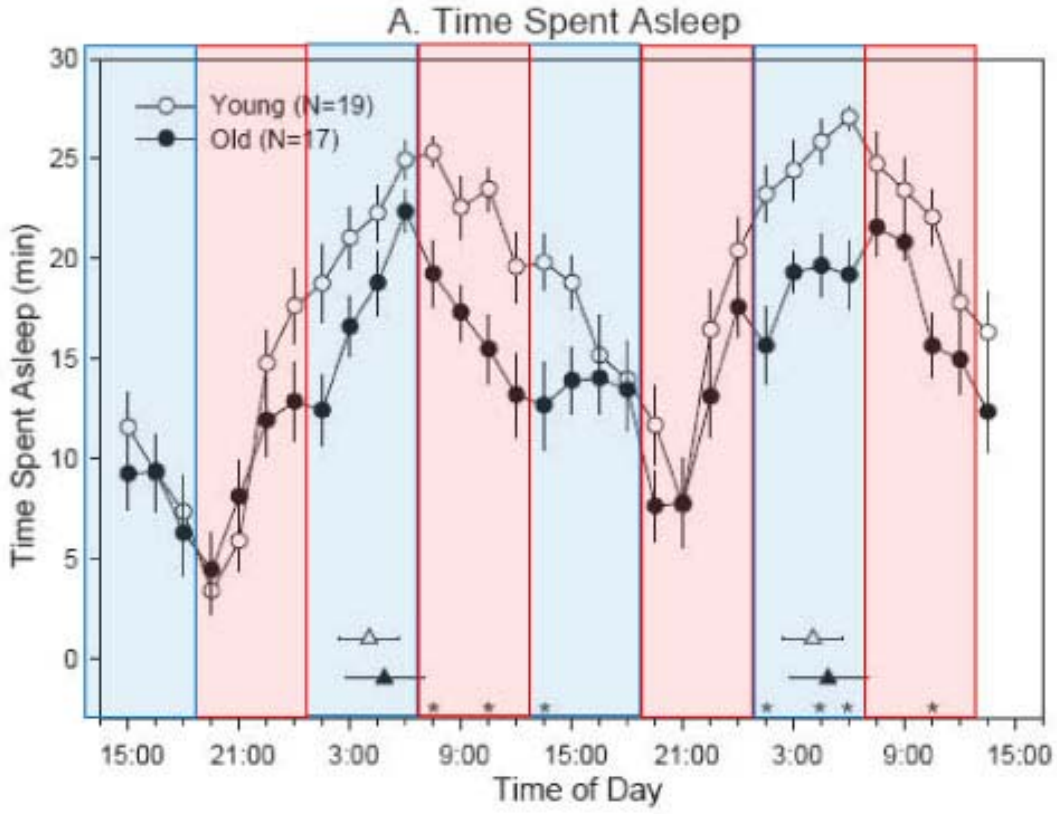

Figure 1 – With the square watch anchored on 2400 h, it is the 1800-2400 shift of the Pilot's watch that has the shortest sleep times on the 90 minute day. The Captain's Watch is in blue; the Pilot's Watch is in red.

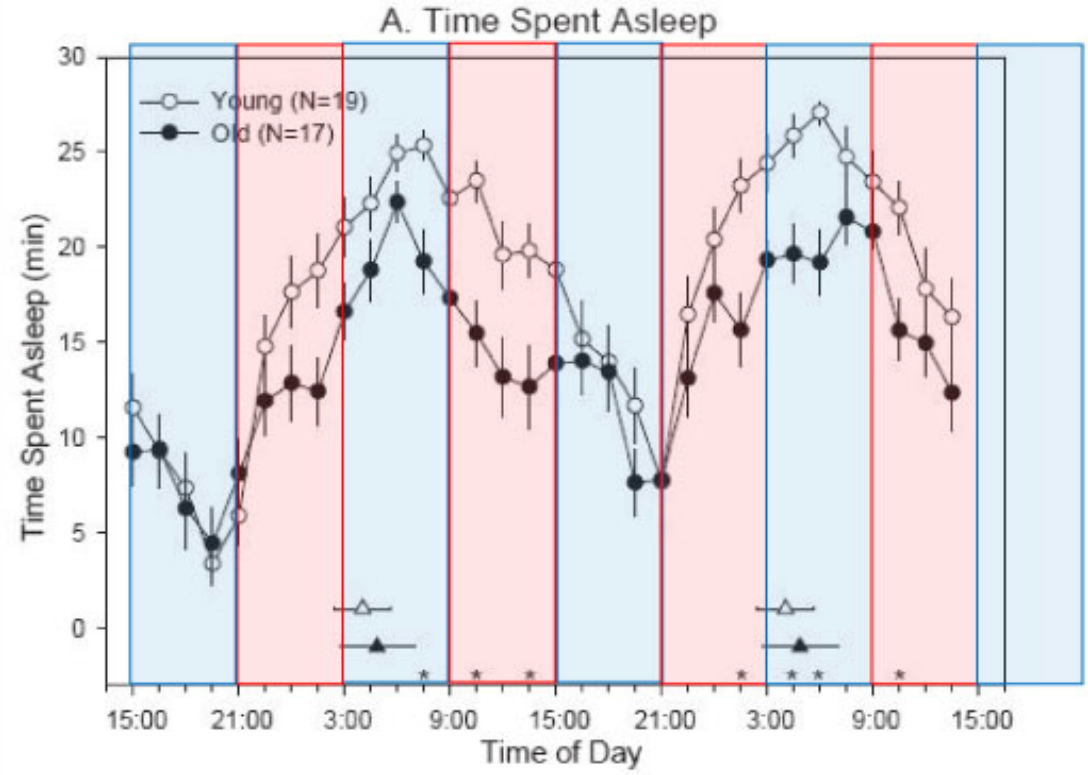

Figure 2 - With the square watch anchored on 0300 h, it is the 1500-2100 shift of the Captain's watch that has the shortest sleep times on the 90 minute day. Overall, with the 3-hour shifted square watch, sleep opportunities may be on average more evenly distributed with respect to sleep propensity and circadian phase as they interact with time awake (homeostatic drive). The Captain's Watch is in blue; the Pilot's Watch is in red.