

## ARIC MANUSCRIPT PROPOSAL FORM

Manuscript #393

1. Title:

The Sleep Heart Health Study--Design, Rationale, and Methods

2. Investigator:

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Study Type: Mainline

Type of Publication: Paper

Analysis Responsibility: Central

3. Introduction:

Obstructive sleep apnea (OSA) is a potentially debilitating condition characterized by repetitive episodes of apnea while asleep, nocturnal oxygen desaturation, excessive daytime sleepiness and loud disruptive snoring (1). Recent epidemiologic data from middle-aged adults indicate that OSA is quite common with a prevalence rate of 4% in men and 2% in women (2). Several studies have implicated OSA as a risk factor for the development of hypertension (3), ischemic heart disease (4), congestive heart failure (5), stroke and consequently premature death (6).

Obstructive sleep apnea, however, may not be an independent risk factor for the development of cardiovascular (CVD) or cerebral vascular disease (CBD). Known CVD and CBD risk factors such as obesity, smoking and smoking commonly are present in those with OSA. Therefore, the apparent association between OSA and CVD or CBD may only result from the effect of these concomitant risk factors.

If it can be shown that OSA is an independent risk factor for the development of CVD and CBD, several other issues remain unresolved. For example, it is unclear whether an increase in propensity to develop CVD and CBD would be limited to only those with frank OSA or whether more subtle forms of sleep related breathing disorders also would confer risk. Furthermore, it is not known whether such factors as race, age, gender and prevalent CVD or CBD would interact with OSA to

alter future CVD and CBD risk. Mechanisms underlying any propensity to develop CVD or CBD with OSA also have not been firmly established.

The Sleep Heart Healthy Study (SHHS) is a longitudinal observational population-based study which is being performed in samples of several existing active epidemiologic cohorts. The principal objective of the SHHS is to determine whether OSA and sleep related breathing disorders are independent risk factors for the development of CVD and CBD. This paper outlines the study design and methods. Detailed descriptions are given in the SHHS Manual of Operations (7).

#### 4. Outline of Paper Submitted In Lieu of Analysis Plan:

- I. Introduction (See Above)
- II. Listing of Primary Hypotheses
- III. Study Design
  - A. Rationale for Using Existing Cohorts
    1. Expense of recruiting new cohort
    2. Efficient use of previously collected cardiovascular risk factor data
    3. Previously enrolled cohorts more likely to volunteer for having a sleep study performed
  - B. General description of Cohorts comprising SHHS--References to be made to previously published methods papers; Also, each description to include projected number of enrolled participants
    1. Description of ARIC and the 2 cohorts in SHHS
    2. Description of CHS and the 3 cohorts in SHHS
    3. Description of Framingham
    4. Description of 3 NYU-Cornell Cohorts
    5. Description of the # Strong Heart Study Cohorts
    6. Description of the 2 Tucson Cohorts
  - C. Sample Size and Power Calculations
  - D. Sampling/Recruitment Priorities
    1. Gender, snoring and minority preferences
    2. Discussion of lower age limit
    3. Discussion of inclusion of prevalent disease
  - E. Description of Protocol
    1. Listing of A variables and discussion of B and C variables
    2. Listing of data collected solely for SHHS--Sleep habits questionnaire, AM Questionnaire, Meds Survey, additional site specific risk factor questions, BP, Weight, Neck Circumference, PSG
    3. Description of Reading Center and Compumedics Sleep Recorder
      - a. Reading Center Description and Method of Data Transmission
      - b. Description of capabilities
      - c. Rationale for selection
      - d. Recording montage
      - e. Algorithms used for scoring of studies
    4. General description of questionnaires and site specific risk factor interview
    5. Techniques used for BP, Weight, Neck Circumference

- F. Follow-up and Mortality and Morbidity Determination--Parent Study Adjudication
- G. Data Management and Quality Assurance Program

#### IV. Conclusion

#### V. References

1. Orr WC, Quan SF. Sleep apnea syndromes--A primer of diagnosis and treatment. CNS, Inc.: Chanhassen, MN, 1991
2. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med* 1993; 328:1230-5.
3. Gislason T, Aberg M, Taube A. Snoring and systemic hypertension--an epidemiologic study. *Acta Med Scand* 1987; 222:415-21.
4. Hung J, Whitford EG, Parsons RW, et al. Association of sleep apnea with myocardial infarction in men. *Lancet* 1990; 336:261-4.
5. Malone S, Liu PP, Holloway R, Rutherford R, Zie A, Bradley TD. Obstructive sleep apnea in patients with dilated cardiomyopathy: effects of continuous positive airway pressure. *Lancet* 1991;338:1480-4.
6. Partinen M, Guilleminault C. Daytime sleepiness and vascular morbidity at seven-year follow-up in obstructive sleep apnea patients. *Chest* 1988; 94:9-24.
7. Sleep Heart Health Study Manual of Operations, SHHS Coordinating Center, Seattle, WA, 1996.