Jackson Heart Study Manuscript Proposal Form

Please read JHS Publications & Presentations protocol before completing this proposal.

ADMINISTRATIVE USE

JHS MS # P0067

Date of Submission: _____ (mm/yy) **Date of Approval:** _____ (mm/yy)

PART I. OUTLINE OF PAPER

1. Title Information

a. Proposal Title: (Please include the phrase "Jackson Heart Study")

Prevalence and determinants of low HDL cholesterol in African Americans: The Jackson Heart Study

b. Abbreviated Title: (≤ 50 characters)

Dyslipidemia in the Jackson Heart Study

c. Suggested key words (Please include JHS, African Americans): JHS, African American, ATP III, LDL cholesterol, HDL cholesteroal, total cholesterol, dyslipidemia

2. Lead Author Name: **Herman A. Taylor, Jr., M.D.**
Institutional Affiliation**:** University of Mississippi Medical Center
Address: Jackson Heart Study
Telephone: 601-368-4650 Fax: 601-368-4651
Email: htaylor@medicine.umsmed.edu

3. Co-authors: (Proposed co-authors email address and/or telephone numbers and proposed responsibilities and/or indicate specific writing assignments. Items not assigned to a co-author are assumed to be the responsibility of the lead author. Non –JHS Lead authors are encouraged to visit the JHS Website http://ccaix.jsums.edu/~jhs/ for information on relevant JHS investigators. JHS may nominate additional author if special expertise for interpreting JHS data is needed).

Name	Contact Information	Responsibilities
Daniel Sarpong	Dsarpong@jsums.edu	Introduction
Meggie Akylbekova	meggiee@jsums.edu	Methods, analysis.
Evelyn Walker	Ewalker@jusms.edu	Discussion
Sharon Wyatt	swyatt@son.umsmed.edu	Discussion
Honey East	heast@medicine.umsmed.edu	Study Design, discussion

Name(s) of JHS investigators from the writing group list above:
All except Honey East

Name(s) of under-representative minorities from the writing group list above:
Tayllor, Sarpong, Walker

4. Background/Rationale :Dyslipidemia are broadly defined abnormalities based on the measurements of an array of lipoprotein cholesterol and plasma lipid measurements

(Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III) 2486-97). Low HDL cholesterol is one of several distinct dyslipidemia which contribute to epidemic CHD in African Americans (Jones et al. 2565-71). Since 1985, the National Cholesterol Education Program (NCEP) has been refining the definitions and criteria for intervention and treatment of low HDL cholesterol and other dyslipidemia based on the results of observational studies and clinical trials (Natarajan et al. 50-57;Schucker et al. 3527-31;Schucker et al. 666-73). It has also undertaken efforts to encourage screening and appropriate treatment when dyslipidemia is diagnosed. The detailed information which is available regarding medical history, lipoprotein cholesterol levels and medication for dyslipidemia in the JHS cohort is essential for determining the true prevalence of low HDL cholesterol, since its level is often influenced by treatment for other dyslipidemia. This report will also investigate how other attributes influence the prevalence of low HDL cholesterol in adult African Americans.

5. Research Hypotheses/Research Questions:

a) Low HDL cholesterol prevalence, as defined by ATP III varies across age and gender in adult African Americans.
b) Low HDL prevalence is high among those with history of coronary heart disease, hypertension and type 2 diabetes after adjustment for age and gender.
c) Low HDL is associated with demographic (age, gender, SES) and lifestyle (BMI, ETOH, CIG) attributes.
d) The most commonly used medications used to treat hypercholesterolemia appear to reduce the prevalence of Low HDL cholesterol.
e) The age and gender specific distribution and percentile thresholds of HDL cholesterol values in the JHS cohort will not differ from those observed in other large African American cohorts.

6. Data: (Visits and variables to be used, sample inclusions/exclusions)
a) Visit 1 lipid derived variables including ATP II and ATP III dyslipidemia definitions.
b) Visit 1 CVD history interview responses (CHD, CVA, CHF, RND, DIA)
c) Visit 1 adjudicated CHD, CVA if available
d) Visit 1 CVD risk factors measurements (BMI,WCF,SBP,DBP,PPR,FBG,TCH,HDL,LDL,TRG,CIG, ETOH)
e) Visit 1 cholesterol awareness, treatment and cholesterol medication codes (medication and dose if available)
f) Visit 1 CVD risk factor derived variables (OBS,HBP,DIB)
g) Visit 1 SES (EDY,INC), gender, age in years, age recode

7. Brief Statistical Analysis Plan and Methods: (Including power calculations, if necessary.)
Data analyses will include frequency distributions of HDL cholesterol by gender and age group. A positive CHD history will be defined by the participants positive response to the relevant history question or by adjudicated prevalent CHD/CVA if available. Participants with positive CHD history may be excluded from some analyses as will those with a history of treatment for

dyslipidemia. Thresholds for low HDL cholesterol will be identified from the literature and applied to the sample and summarized as prevalence estimates, by gender and age. Other thresholds identified or suggested by inspection of the frequency distributions of HDL cholesterol may also be applied. Associations with independent variables listed above (5.b,c) will be identified and tested using multivariable logistic regression, with low HDL as the dependent variable. Relationships may also be investigated using multiple linear regression with HDL cholesterol level as the dependent variable. Identified relationships will be summarized as prevalence rates for various levels of the attributes identified as associated with low HDL cholesterol.

6. **References:** (Maximum 15)

Reference List

Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). JAMA 285.19 (2001): 2486-97.

Jones, D. W. et al. "Risk factors for coronary heart disease in African Americans: the atherosclerosis risk in communities study, 1987-1997." Arch.Intern.Med. 162.22 (2002): 2565-71.

Natarajan, S. et al. "Cholesterol measures to identify and treat individuals at risk for coronary heart disease." Am.J.Prev.Med. 25.1 (2003): 50-57.

Natarajan, S. and P. J. Nietert. "National trends in screening, prevalence, and treatment of cardiovascular risk factors." Prev.Med. 36.4 (2003): 389-97.

Prisant, L. M., C. Thurmond, and V. J. Robinson. "Treating hyperlipidemia in African Americans." Ethn.Dis. 10.3 (2000): 334-42.

Schucker, B. et al. "Change in public perspective on cholesterol and heart disease. Results from two national surveys." JAMA 258.24 (1987): 3527-31.

Schucker, B. et al. "Change in cholesterol awareness and action. Results from national physician and public surveys." Arch.Intern.Med. 151.4 (1991): 666-73.

PART II. AUTHOR CONTRIBUTIONS

9 Have all co-authors reviewed and approved this document? **Yes** Yes (required)

10. . Does the lead author (or designee) agree to present findings at a JHS Colloquium or Seminar? **Yes** Yes (required)

Note: A lay summary is required when submitting the completed manuscript draft for JHS and NHLBI approvals.

PART III. ADDITIONAL INFORMATION

11. Type of Study:

X Full Cohort _____ Family Study _____ Sub-Study
_____ Ancillary Study _____ Case Control _____ARIC/JHS Combined Cohort
_____ Other (list):

12. Type of Data:

_____ Longitudinal X Cross-Sectional _____ Other (list):

13. Location of Statistical Analysis:

X Central (by Jackson Heart Study Staff)
_____ Local (list site) _____

14. Genetic Information:

a. Do you propose use of data from a participant's DNA? _____ Yes (see b)
X No
b. If yes, for a primary aim or secondary aim of JHS? (check one or both)
_____ Primary Aim (heart, vascular disease) _____ Secondary Aim (other conditions)

15. Conflict of Interest

a. Are these analyses to involve a for-profit corporation? _____Yes __X___No
b. Do you or any member of your Writing Group intend to patent any process, aspect of outcome of these analyses? _____Yes ____X___No

16. Data Sharing Agreement

a. Has the Lead Author and any co-authors who will have direct access to JHS data signed the JHS Data Sharing Agreement? ___Yes___Yes (Required)

17. JHS Manuscript Overlap

The Lead Author has reviewed all existing JHS manuscripts / manuscript proposals and found:

a. No similar manuscripts / proposals __X____Yes
b. The following manuscripts / proposals with similarities: (List MS # title and Lead Author below)

18. Note: Completion of manuscript preparation is expected in <u>less than three years</u>. The manuscript proposal will expire if no manuscript draft is submitted for JHS review at the end of the three years from date of approval. If additional time is needed after three years, please contact JHS for extension.